

1. General Product Identification Information

Single-use product, supplied in kit form, sterile – sterilized by ethylene oxide,

Forbidden to reuse

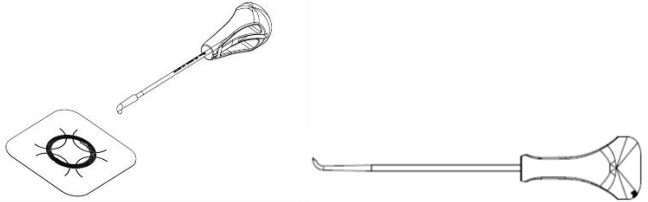
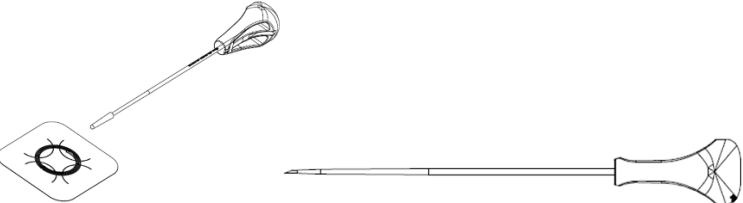
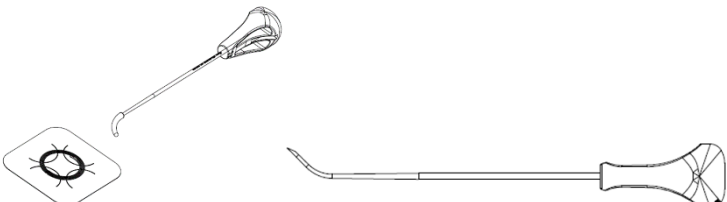
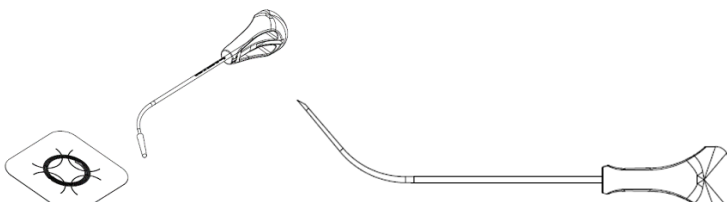
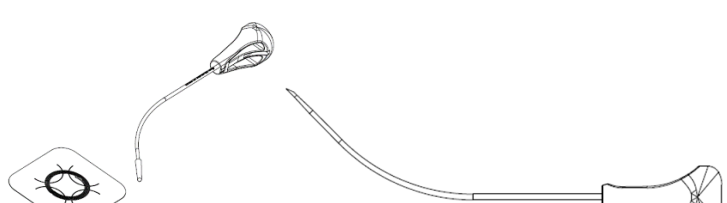
Product shelf life: 3 years

Technical Name: SUTURE PASSER

Trade Name: Micro EasyPass – Suture Passer Family

1.1 Component Relationship

Table 01 – List of components

CODE	DESCRIPTION	IMAGE
335-99	MICRO EASYPASS - SHORT CURVED MICRO SUTURE PASSER	
335-100	MICRO EASYPASS - STRAIGHT MICRO SUTURE PASSER	
335-200	MICRO EASYPASS - SMALL CURVED MICRO SUTURE PASSER	
335-300	MICRO EASYPASS - LARGE CURVED MICRO SUTURE PASSER	
335-600	MICRO EASYPASS - EXTRA LARGE CURVED MICRO SUTURE PASSER	

2. Description of the physical principle and fundamentals of the product's technology for its foundation, its action and function

2.1 Product Description

The product's mechanism of action is to take and bring the suture and manipulate it through the soft tissue during arthroscopic procedures. It can be used with any type or size of suture thread and in conjunction with anchors or screws (including suture pre-assembled to an anchor).

2.2 Indication for use

The product aims to allow the manipulation of the suture in soft, arthroscopic and open tissue repair procedures.

2.3 Composition

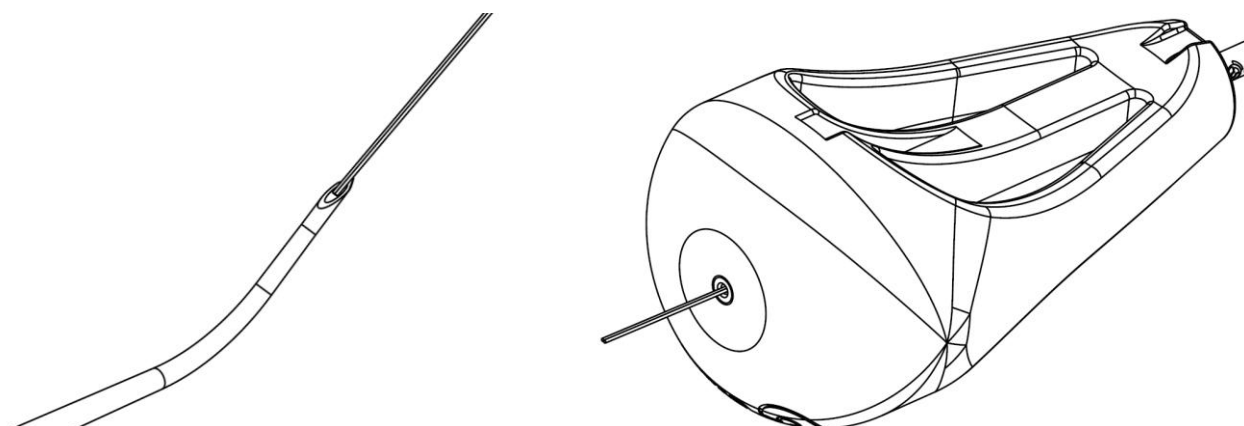
The Micro EasyPass – Family of Micro Suture Guides is manufactured in Stainless Steel – ASTM F899, Polyacetal Copolymer – ASTM F1855 and Nitinol – ASTM F2063

3. Instruction for the correct use of the product and indication of training

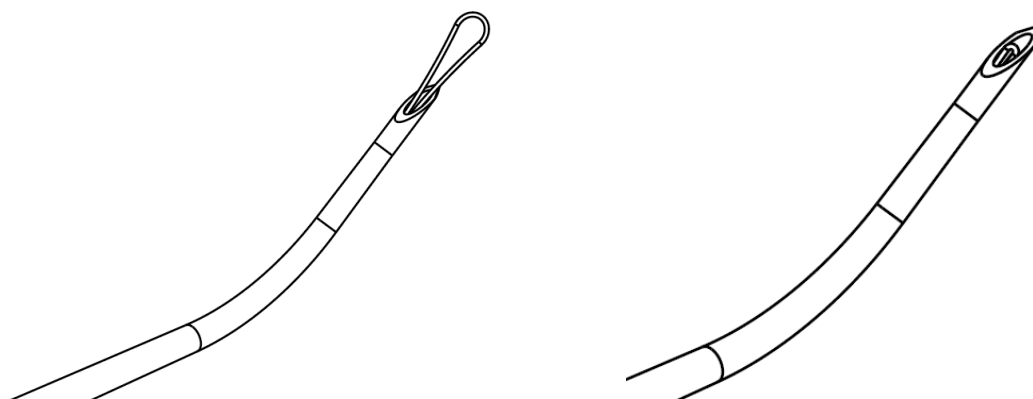
The Micro EasyPass – Family of Micro Suture Passers should be used exclusively by a qualified and trained professional in surgical techniques that involve the passage of sutures in soft tissues and bone tunnels. Its proper use is conditioned to the surgeon's experience with this type of procedure, and it is essential that the surgical technique adopted is aligned with his training and professional practice.

The following are the steps for utilizing the product:

- a) Select the Micro EasyPass model, according to the surgical planning.
- b) Pass the nitinol loop through the needle as follows:
 - Insert the end with the tips of the nitinol loop into the tip of the needle until it comes out of the handle;



- Check to see if the end with the loop is emerging at the tip of the needle.



- c) As the loop is fully retreated, introduce the dowel through the portal or incision, advance the loop in the region where the tape or suture that will be transported is positioned.
- d) Next, insert the tape or suture into the nitinol loop and then pull the nitinol loop until it is stable at the needle tip of the Micro EasyPass. The tape or suture should not be pulled into the needle and should only be attached to the end of the Micro EasyPass by the nitinol loop.
- e) Use the Micro EasyPass to transport the suture or tape through the soft tissues or bone tunnel, releasing it in the region where it will be used.

4. Precautions, restrictions, warnings, special care, clarification on the use of the product

4.1 Additional information on the procedure before using the product

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

The instruments must be used according to specific surgical techniques, adopted by a duly trained and qualified professional in orthopedic surgical procedures.

Extreme care must be taken to ensure that the surgical instrument remains in good working condition. Any surgical techniques applicable to the use of this system should be carefully followed. Misuse of the surgical instrument may cause corrosion, deformation and/or fracture of any or all sections of the surgical instrument, which may inhibit its proper functioning.

Do not use this instrument for any action for which it was not designed. Surgical instruments should be treated like any precision instrument and should be carefully packaged.

Improper use of surgical instruments, as well as the use of damaged surgical instruments, can cause injury or damage to the patient or operating room personnel. If damaged, do not reuse; replace it.

Care in distribution, storage, transportation, cleaning, storage, conservation and traceability must follow the Good Practices for Storage and Distribution of Medical Products, according to the current resolution. Surgical instruments should be stored in a dry, ventilated, clean place, free from the action of bad weather and at room temperature.

4.2 Warning associated with the event of a component falling

If the product falls, the product must be rendered unusable and disposed of according to the procedure of the medical-hospital area or regional legislation or according to the Instructions of the Hospital Infection Control Commission – CCIH.

4.3 Procedure related to disposal that ensures the unusability of the product

The product that for some reason was not used during the surgical act and had the packaging opened, or suffered damage and/or fall cannot be reused and/or restyled, and must be disposed of at the hospital itself according to the medical-hospital procedure and/or local legislation or according to the instructions of the Hospital Infection Control Commission - CCIH.

The methods and procedures for disposing of the medical product must ensure its complete decharacterization, preventing any possibility of its reuse. The decharacterization of the medical product is the sole responsibility of the hospital institution, as well as the disposal methods and procedures used.

4.4 Contraindications

The use of the product is contraindicated for any surgical procedure other than application in soft, arthroscopic and open tissue repair surgery. Do not use a damaged or poorly maintained instrument.

5. Traceability, form of presentation, sterilization, expiration, storage, handling and transport

5.1 Form of presentation of the medical product

The Micro EasyPass – Family of Micro Suture Guides is individually marketed, single-use, sterile and presented in four packaging levels.

The Micro EasyPass – Family of Micro Suture Threaders is packaged in a double surgical-grade envelope, image 1, constituting the primary and secondary packages, duly labeled on the back with a sensitive indicator of sterilization by ETO, where they are supplied unitarily. The product is then packaged in a plasticized, printed paper box, which receives a seal with a sensitive indicator of sterilization by ETO, label and adhesive safety seal, constituting the tertiary packaging, later wrapped by a polyolefin film, heat shrinkable constituting the quaternary packaging of the product. The product includes: 5 traceability labels and a manual with user guidelines on how to access, free of charge, the Instructions for Use of the product in non-printed format (digital) and if the user requests it, the printed version of the Instructions for Use will be made available free of charge, including shipping without any charge. This information is compatible on the product labeling.



Image 1: Illustrative image of sterile packaging

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 version em vigor. aprobado por la Anvisa	
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Caso necessite receber uma versão impressa da IU, sem custo adicional, inclusive de envio, solicite gratuitamente pelo e-mail: sac@gmreis.com.br ou pelo 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 labeling	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

Image 2: Manual that comes with the product.

5.2 Product traceability procedure

The identification and traceability of the product is ensured through a set of 05 adhesive labels, as shown in image 3, provided on the package along with the access guide to the Instruction for Use and the product, bringing information about the product, such as: name, model, code, batch, product registration and manufacturer identification. In this way, it is possible to take the reverse path and reach the production, raw material, suppliers and other quality control items established in the GMReis Quality Management System.

It is recommended that traceability labels be affixed in the following locations:

- Label number 1, mandatorily, in the patient's clinical record;
- Label number 2, in the report delivered to the patient;
- Label number 3, on the tax documentation that generates the collection to the paying source;
- Label number 4, made available for supplier control (historical record of distribution);
- Label number 5, made available for surgeon control.

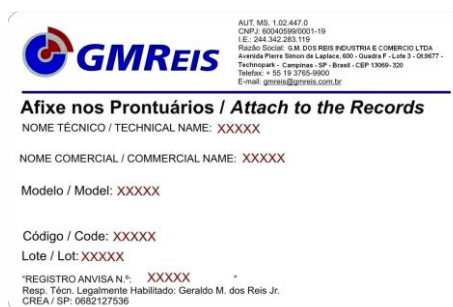


Image 3: Traceability label

5.3 Sterilization method

The Micro EasyPass – Family of Micro Suture Passers is supplied sterile, sterilized by ethylene oxide (ETO), according to ISO 11135, and must be kept in its original packaging until the moment of use, following medical-hospital asepsis procedures. The product is for single use only and should not be resterilized, as this may compromise its original physicochemical and mechanical characteristics, resulting in the loss of the performance expected for its intended use and, consequently, may generate risks to the patient.

5.4 Validity

The shelf life of the product is 3 years after the date of sterilization.

5.5 Handling, conservation, storage and transport

The product must be stored, preserved, handled and transported in its original packaging until the moment of use in a clean, dry environment, free from the action of weather and at room temperature. During transport, falls, bumps or mechanical damage must be avoided.

Before removing the components from the product, it must be checked that the original packaging remains intact and the expiration date is within the period allowed for use, ensuring its sterility. If the packaging is violated, damaged, deteriorated or the expiration date has expired, the product must be rendered unusable and discarded according to the procedure of disuse and disposal.

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

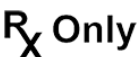
If the product packaging is opened, or for any reason the product is not used, all product components must be rendered useless and discarded according to the procedure of disuse and disposal.

The storage, handling, conservation and transport of the product outside the specified conditions can generate risks to the procedure and the patient.

5.6 Labeling Symbolology

The graphic symbols used in the labeling are in accordance with the ABNT NBR ISO 15223-1 Standard, as shown in table 2:

Table 02: Labeling symbolology

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Date of Manufacture		Care
	Maker		Shipment or batch code
	Use Up to Date		Protect from sunlight
	Keep dry		Refer to the instructions for use or consult electronic instructions for use
	Single-use product Do not reuse		Sterilized with ethylene oxide
	Do not use if packaging is damaged and refer to instructions for use		Do not re-sterilize
	Prescription only		



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Micro EasyPass – Suture Passer Family

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6. Restrictions on reuse and reprocessing

Even if it appears to be in perfect condition, after reprocessing the product may lose its physical and mechanical properties, not presenting the expected performance for the intended use, which may put the health of patients and health establishment professionals at risk.

"The manufacturer recommends single use"

7. Specific guidelines for reporting adverse events and technical complaints

If the Micro EasyPass – Family of Micro Suture Threaders presents a specific unpredictable risk, is out of its specifications or is generating any dissatisfaction, notify GM Reis Customer Service (SAC) directly. The product must be sent clean and packed in a plastic bag, duly identified and with the description of the non-conformity to the following address: **Av. Pierre Simon de Laplace, 600 – Lote 3 – Quadra F – Quarteirão 9677 – CEP 13069-320 – Condomínio Technopark - Campinas, SP, Brazil** or notify directly at Tel.: (0XX19) 3765-9900 / E-mail: sac@gmreis.com.br.

USER ALERT

These Instructions for Use are available in non-printed format, through the manufacturer's electronic address: <http://www.gmreis.com.br/produtos/IFU>, and can be checked in the search field by the commercial name and registration number with Anvisa, described on the product packaging label. Always check the correlation of the version of the Instruction for Use with the version informed 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 it for free by e-mail: sac@gmreis.com.br.

GM dos Reis Indústria e Comércio Ltda.

Avenida Pierre Simon de Laplace, nº 600 - Lote 3 - Quadra F - Quarteirão 9677

Bairro TECHNOPARK - CEP: 13069-320 – Campinas – SP - BRASIL

Operating Authorization – AFE nº 1.02.477 - 0

C.N.P.J/M.F: 60.040.599/0001-19 / I.E: 244.342.283.119

Email: qualidade@gmreis.com.br

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Anvisa Registration: 10247700132 – rev.04

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Micro EasyPass – Suture Passer Family

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Qualified Technical and Legal Responsible:

Geraldo Marins dos Reis Júnior

CREA – SP nº 0682127536

Revision History

Rev. 00 of 04/07/2019 – Cancelled

Rev. 01 of 08/26/2019 – Product inclusion

Rev. 02 of 12/20/2020 – Product inclusion

Rev. 03 of 20/08/2021 – Change of trade name

Rev. 04 of 09/10/2025 – Change in the commercial presentation