

1. General Product Identification Information

Single-use, sterile product – sterilized by Ethylene Oxide (ETO)

Reprocessing Prohibited

Reuse Prohibited

Product shelf life: 3 years

Trade Name: Suture Passer

1.1 Components

CODE	DESCRIPTION	IMAGE
312-200	Suture Passer - Suture Transporter	

Table 1 – Model

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

2.1 Product Description

The Suture Passer consists of a thin plastic tube and a stiffened suture thread with a loop at one end, which is used to capture and hold suture wires in order to pass them through bone portals and tunnels. The loop expands when exposed outside the tube and contracts when retracted into the tube. The loop moves in relation to the tube manually.

2.2 Indication for Use

The Suture Passer is intended to facilitate the passage of sutures through portals and bone tunnels, in arthroscopic procedures and in traditional open surgeries, in ligament and tendon reconstructions.

2.3 Composition

The Suture Passer – Suture Transporter is composed of a tube and a wire, both in UHMWPE Polyethylene – ASTM F648.

2.4 Criteria for the selection of the size, format and design associated with the success of the procedure

The correct selection of the model is extremely important, considering the biomechanical aspects and the anatomy to be treated. The surgeon has a choice of curvatures, diameters and lengths, which should be chosen, according to the characteristics of the patients, for each case.

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

The Suture Passer consists of a thin plastic tube and a stiffened suture thread with a loop at one end, which is used to capture and hold suture wires in order to pass them through bone portals and tunnels. The loop expands when exposed outside the tube and contracts when retracted into the tube. The loop moves in relation to the tube manually.

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

4.1 Instruction for correct use

- 4.1.1 Remove the Suture Passer from the sterile packaging.
- 4.1.2 The product is already assembled and ready for use and can be used to transport sutures.

4.2 Indication of training

Only surgeons qualified and trained in orthopedic surgery should handle this product.

Note: The surgeon should be aware of all the recommendations described in the "instruction for use" of the product and other information described on the labeling.

5. Precautions, restrictions, warnings, special cautions, and clarification regarding the use of the product

5.1 Patient Instructions

The patient should be warned by the surgeon in charge about the limits of his/her activities and about his/her rehabilitation in order to protect the surgery performed.

It is the responsibility of the surgeon in charge to make postoperative recommendations, follow-ups, clinical and radiological evolution of the patient.

5.2 Forming Limit (Modeling)

The Suture Passer is not designed to withstand overloads and mechanical forming stresses (twisting and bending). If exercised during use, they compromise their mechanical characteristics, which can lead to early failure, as well as breakage during use.

5.3 Procedure and case of product drop

If the product falls, it should not be used and should be unusable and discarded according to the unusability and disposal procedure.

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5.4 Procedure related to disposal that ensures the product is unusable

The product that, for some reason, was not used during the surgical procedure and had the packaging opened, or suffered damage and/or falls, cannot be reused and/or restyled, and must be discarded in the hospital itself according to the medical-hospital procedure and/or local legislation or even 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 mischaracterization, preventing any possibility of its reuse. The mischaracterization of the medical product is the sole responsibility of the hospital institution, as well as the methods and disposal procedures used.

5.5 Contraindications

Do not use the Suture Passer for applications other than the purpose for which it was developed.

6. Traceability, form of presentation, sterilization, storage, handling and transport

6.1 Marking

The products are identified by laser marking with the following information:

- GMReis brand logo;
- Product code;
- Batch of the product.

6.2 Product Traceability Procedure

The identification and traceability of the Suture Passer are ensured through a set of 05 adhesive labels provided in the package (see illustrations below), along with the Instruction for Use and the device, bringing information about the product, such as: name, model, code, batch, product registration and identification of the manufacturer. In this way, it is possible to take the opposite path and reach the production, raw material, suppliers and other quality control items established in the GMReis Quality System. Traceability labels shall be affixed in the following locations:

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

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E-mail: gmreis@gmreis.com.br

Afixe nos Prontuários / Attach to the Records

NOME TÉCNICO / TECHNICAL NAME: XXXXX

NOME COMERCIAL / COMMERCIAL NAME: XXXXX

Modelo / Model: XXXXX

Código / Code: XXXXX

Lote / Lot: XXXXX

*REGISTRO ANVISA N.º: XXXXX

Resp. Técn. Legalmente Habilitado: Geraldo M. dos Reis Jr.
CREA / SP: 0682127536

Image 2: Traceability label.

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

6.3 Form of presentation of the medical product

The Suture Passer is marketed in individual, single-use, sterile form and presented in 4 levels of packaging, described below:

The Suture Passer is packaged in double surgical grade paper, constituting the primary and secondary packaging containing a label and a sensitive indicator of ETO sterilization. The product is packaged in a plasticized, printed paper box, which receives a label and a security adhesive seal, constituting the tertiary packaging. The paper box is wrapped in a polyolefin film, heat shrinkable constituting the quaternary packaging of the product. Included with the product: 5 traceability labels and a manual on how the user can obtain the Instructions for Use of the product, through the non-printed format, at no additional cost, including shipping. This information is compatible on the product labeling.

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 este 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	
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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	PT - Guia para acesso das Instruções de Uso GMReis (IFU) EN - GMReis instructions for Use (IFU) access guide ES - Guía para acceder a las instrucciones de uso (IFU) IFUGMREIS - Rev.01

Image 3: Manual that comes with the product.

6.4 Sterilization Method

The Suture Passer is supplied sterile, being sterilized by ethylene oxide (ETO) according to the ISO 11135 standard and must be kept in its original packaging until the moment of use, following the procedures of hospital medical asepsis. The product is for single use, and should not be re-sterilized, as this entails the risk of losing its original physical, chemical and mechanical characteristics, so that the product will not present the performance attributed to its intended use, which may generate risks to the patient.

6.5 Shelf Life

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

6.6 Handling, conservation, storage and transport

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

The Suture Passer must be handled with great care to avoid sudden shocks, falls and other risks and/or imperfections that affect its quality and the user's safety.

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

Handling of the Suture Passer must be carried out exclusively by professionals in the medical and hospital field, duly trained, qualified and familiar with the technique and procedures involved.

6.7 Labeling symbology

The graphic symbols used in the labeling are in accordance with the ISO 15223-1 Standard, as follows:

Table 5: Labeling Symbols			
SYMBOLS	DESCRIPTION	SYMBOLS	DESCRIPTION
	Date of manufacture		Caution
	Manufacturer		Batch code
	Use-by date		Keep away from sunlight
	Keep dry		Consult instructions for use or consult electronic instructions for use

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	Do not re-use		Sterilized using ethylene oxide
	Do not use if package is damaged and consult instructions for use		Do not resterilize
R_x Only	Prescription only		

7. Restrictions on reuse and reprocessing

The reprocessing of the Suture Passer is not allowed, even if it appears to be in perfect condition, as 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 professionals at risk.

8. Specific guidelines for reporting adverse events and technical complaints

If the Suture Passer presents a specific unforeseeable 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 a description of the non-conformity, to the following address: Av. Pierre Simon de Laplace, 600 – Lote 3 – Quadra F – Quadreirão 9677 – CEP 13069-320 – Condomínio Technopark - Campinas, SP, Brazil or notify directly at Tel.: (0XX19) 3765-9900 / E-mail: sac@gmreis.com.br.

ALERT TO USER

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 trade name and registration number at Anvisa, described on the label of the product packaging. Always check the correlation of the version of the Instruction for Use with the version stated 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 free of charge by e-mail: sac@gmreis.com.br.

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SUTURE PASSER
EN

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Qualified Technical and Legal Responsible:

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Revisions History

Rev. 00 from 06/19/2024 – Initial