

1. General Product Identification Information

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

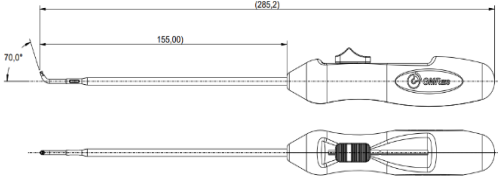
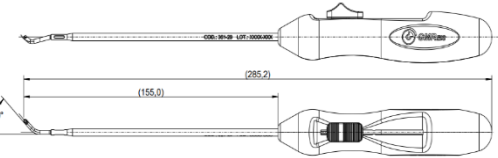
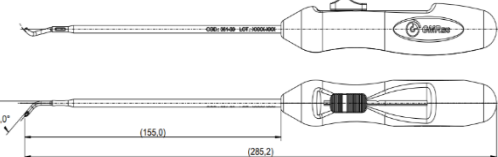
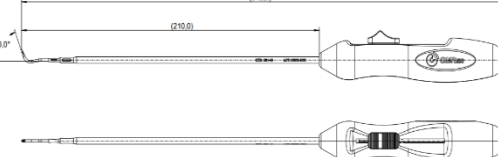
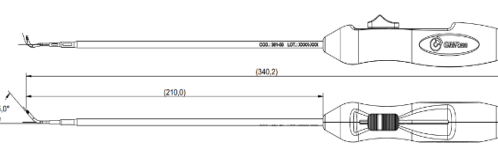
Reprocessing Prohibited

Reuse Prohibited

Product shelf life: 3 years

Trade Name: Suture Fisher

1.1 Component Relationship

CODE	DESCRIPTION	IMAGE	SPECIFIC INDICATION FOR USE
361-10	SUTURE FISHER - CRESCENT SUTURE HOLDER		Passing and pulling sutures in repairs of ligament injuries: shoulder, ankle, knee, wrist and elbow
361-20	SUTURE FISHER – SUTURE HOLDER 45° TO THE RIGHT		Passing and pulling sutures in repairs of ligament injuries: shoulder, ankle, knee, wrist and elbow
361-30	SUTURE FISHER – SUTURE HOLDER 45° TO THE LEFT		Passing and pulling sutures in repairs of ligament injuries: shoulder, ankle, knee, wrist and elbow
361-40	SUTURE FISHER HIP - CRESCENT SUTURE HOLDER		Passing and pulling sutures in the hip region
361-50	SUTURE FISHER HIP - SUTURE HOLDER 45° TO THE RIGHT		Passing and pulling sutures in the hip region

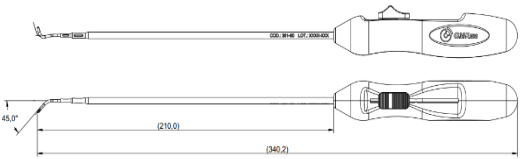
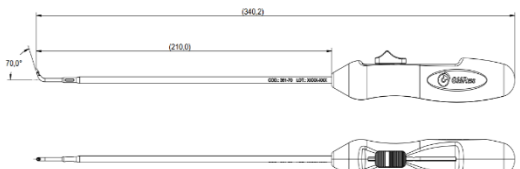
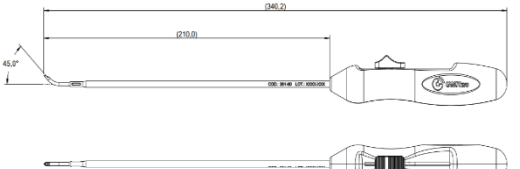
361-60	SUTURE FISHER HIP - SUTURE HOLDER 45° TO THE LEFT		Passing and pulling sutures in the hip region
361-70	CAPLOCK – CAPSULAR PASSER 70°		Passing and pulling sutures in the hip region
361-80	CAPLOCK – CAPSULAR PASSER 45°		Passing and pulling sutures in the hip region

Table 1 – Models

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 Fisher is made up of disposable suture grippers intended for manipulation and assistance in performing sutures, a variety of models with different angles and curvatures that allow sutures to be placed in different anatomical regions. The tip of the suture grippers has a hook profile to manipulate the suture, which when advancing the button forward will expose and open the fixation hook, and when returning with the button backwards will retract and close the fixation hook, thus allowing handling and performing sutures. Due to its low-profile design and sharp tip, it allows orthopedic procedures to be performed through portals, aiming to optimize surgical time, speeding up and facilitating suturing, allowing sutures to be performed easily, quickly and with less damage or tissue compromise.

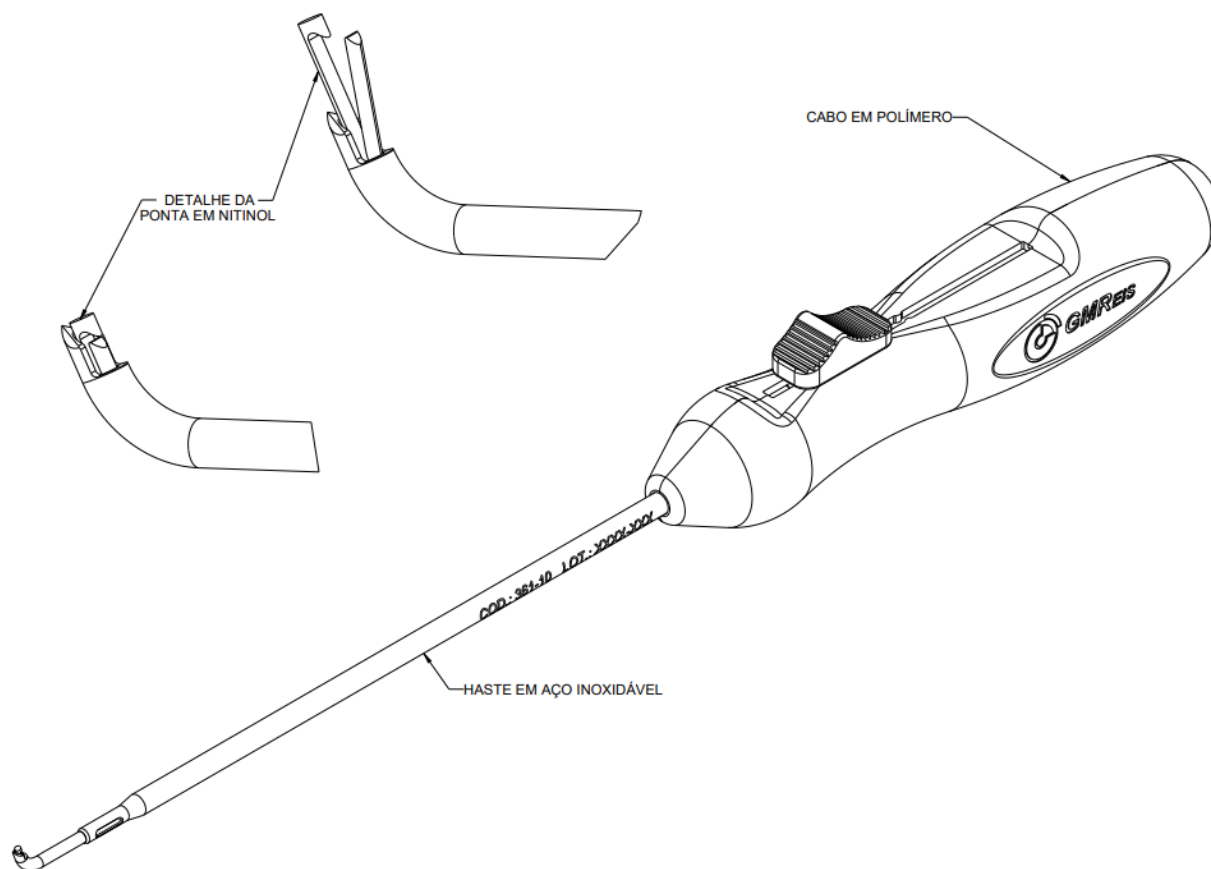


Image 1: Illustrative image of the Suture Fisher

2.2 Indication for use

The Suture Fisher is intended to be used to assist in the manipulation and placement of sutures in different anatomical regions in arthroscopic surgical procedures.

2.3 Composition

The Suture Fisher has a polymer handle, stainless steel shaft and nitinol claw.

- 2.3.1 Polyacetal copolymer handle, in accordance with ASTM F1855 - Standard Specification for Polyoxymethylene (Acetal) for Medical Applications.
- 2.3.2 304 stainless steel shaft, in accordance with ASTM F899 - Standard Specification for Wrought Stainless Steels for Surgical Instruments.
- 2.3.3 Nitinol claw, in accordance with ASTM F2063 - Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants.

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.

	INSTRUCTIONS FOR USE Suture Fisher		SUTURE FISHER EN	
		Sheet:	4 of 8	

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

The Suture Fisher was designed for use with suture wires and/or tapes, sold separately, not subject to this registration.

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 Fisher from the sterile packaging.
- 4.1.2 Make sure that the device is functional, that advancing the button forward will expose and open the fixing hook, and returning with the button backwards will retract and close the fixing hook.
- 4.1.3 With the tip retracted, insert the rod through the portal or through the tissue to be sutured, advance the button forward opening the claw and position the suture wire and/or tape inside the claw, move the button back closing the hook and retract the suture wire and/or tape into the rod.
- 4.1.4 Repeat (**item 4.1.3**) as many times as necessary in order to perform the desired suture in the desired location.
- 4.1.5 At the end of the manipulation and/or suture, retract the claw and remove the device from the surgical site.

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 Fisher 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.

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 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 methods and disposal procedures used.

5.5 Contraindications

- Do not use the Suture Fisher for applications other than the purpose for which it was developed.
- Do not reuse the Suture Fisher.

6. Traceability, form of presentation, sterilization, storage, handling and transport**6.1 Marking**

Os produtos são identificados através de marcação a laser com as seguintes informações:

- Logotipo da marca GMReis.
- Código do produto;
- Lote do produto.

6.2 Product Traceability Procedure

The identification and traceability of the Suture Fisher 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.

	INSTRUCTIONS FOR USE Suture Fisher		SUTURE FISHER EN	
			Sheet:	6 of 8



AUT. MS. 1.02.447.0
 CNPJ: 60040590/0001-19
 I.E.: 244.342.283-119
 Razão Social: G.M. DOS REIS INDUSTRIA E COMERCIO LTDA.
 Avenida Pierre Simon de Laplace, 900 - Quadra F - Lote 3 - 045677 -
 Technopark - Campinas - SP - Brasil - CEP 13069-320
 Telefone: + 55 19 3765-6900
 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 Fisher is marketed in individual, single-use, sterile form and presented in 4 levels of packaging, described below:

The Suture Fisher 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 version em vigor, aprobado por la Anvisa	
No campo busca, procure pelo nº do Registro 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 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 em el etiquetad	ES - Guia 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 Fisher 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

	INSTRUCTIONS FOR USE Suture Fisher		SUTURE FISHER EN Sheet: 7 of 8	
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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 Fisher must be maintained, handled and transported in such a way as to prevent any damage or alteration to its characteristics and packaging.

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

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

The handling of the Suture Fisher must be done exclusively by professionals in the medical-hospital area, 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
	Do not re-use		Sterilized using ethylene oxide
	Do not use if package is damaged and consult instructions for use		Do not resterilize
	Prescription only		

	INSTRUCTIONS FOR USE Suture Fisher		SUTURE FISHER EN	
		Sheet:	8 of 8	

7. Restrictions on reuse and reprocessing

The reprocessing of the Suture Fisher 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 Fisher 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.

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

Autorização de Funcionamento – AFE nº 1.02.477 - 0

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

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Issuance date: 06/07/2024

Qualified Technical and Legal Responsible:

Geraldo Marins dos Reis Júnior

CREA – SP nº 0682127536

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Rev. 00 from 06/07/2024 – Initial