

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: ACCESS FIT – Suture Passer

1.1 Components List

CODE	DESCRIPTION	IMAGE	SPECIFIC INDICATION FOR USE
359-200	ACCESS FIT – STRAIGHT SUTURE PASSER		Passing, manipulating and retrieving sutures in the repair of injuries in the knee, shoulder and hip regions in orthopedic surgical procedures
359-210	ACCESS FIT – RIGHT SUTURE PASSER		
359-220	ACCESS FIT – LEFT SUTURE PASSER		

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

2.1 Product Description

ACCESS FIT is a manual and sterile suture passer, used to perform minimally invasive orthopedic surgical procedures, intended to pass, manipulate and recover the suture through the tissue at various angles and thicknesses. Its design aims to reduce tissue trauma during the procedure, facilitating a faster and more comfortable recovery for patients.

With its anatomical adaptability, ACCESS FIT allows safe and precise access to diverse anatomies, including knee, shoulder and hip joints. It has a reliable fixation system, providing stability throughout surgical suture procedures.

ACCESS FIT has 3 different tip configurations (straight, left and right), allowing access to different regions and tissues. This possibility of different tips offers greater flexibility in accessing the surgical site, being able to meet specific patient and/or procedure needs.

2.2 Indication for Use

The ACCESS FIT is indicated for passing, manipulating and retrieving sutures in the repair of injuries in the knee, shoulder and hip regions in orthopedic surgical procedures

2.3 Composition

ACCESS FIT is composed of a polymer handle in accordance with NBR ISO 16061, a stainless steel rod and claw in accordance with ASTM F899 and a nitinol needle in accordance with ASTM F2063.

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 important, considering the biomechanical aspects and the anatomy to be treated. The surgeon has three versions of ACCESS FIT to choose from, namely: straight, curved to the left or curved to the right. Selection will depend on the location of the injury to be repaired and according to usage criteria..

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

ACCESS FIT was designed for use with suture threads and/or tapes, sold separately, which are not the subject of 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 ACCESS FIT from the packaging;

4.1.2 Start the initial test procedure:

4.1.2.1.1 Activate the trigger until the end of the switch. The upper jaw must be completely closed, and the needle must be advanced above the jaws;

4.1.2.1.2 Release (release) the trigger and observe the claw returning to the initial position. In this position, the upper jaw must be completely open, and the needle must be completely retracted with the tip completely retracted into the lower jaw, not causing any type of obstruction in the passage of the suture thread/tape (lower jaw).

4.1.3 After initial testing, position the suture thread or tape in the lower jaw socket;

4.1.4 Squeeze the trigger to the first stage for jaw closure (without needle advancement);

4.1.5 Insert the ACCESS FIT rod into the access and position the jaws close to the suture point;

4.1.6 Release the trigger (opening the jaws) and perform the suture by retightening the trigger until the end of the switch to fix the tissue and advancing the needle with suture thread/tape;

4.1.7 Release the trigger (jaw opening), move the rod away from the point;

4.1.8 Re-tighten the trigger to the first stage to close the jaws (without needle advancement) and remove the rod through the access;

4.1.9 Repeat the procedure as many times as necessary to complete the desired suture;

4.1.10 At the end of the procedure, discard the ACCESS FIT.

ATTENTION

Single use product do not reuse or resterilize ACCESS FIT.

4.2 Indications 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 must be warned by the responsible surgeon about the limits of their activities and their rehabilitation in order to protect the surgery performed.

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

5.2 Forming Limit (Modeling)

ACCESS FIT was not designed to withstand overloads and mechanical shaping efforts (torsion and bending). If exerted during use, they compromise its 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 is dropped, it must not be used and must be rendered unusable and discarded in accordance with the unusable 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

5.5.1 Do not use ACCESS FIT for applications other than the purpose for which it was developed.

5.5.2 Do not reuse ACCESS FIT.

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

6.1 Marking

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

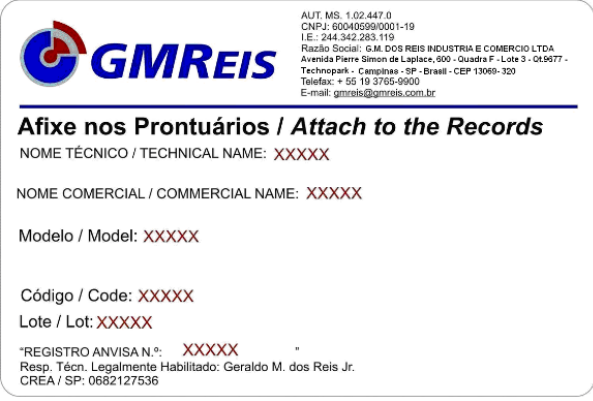
- GMReis brand logo.
- Product code;
- Batch of the product.

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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.



AUT. MS: 1.02.447.0
 CNPJ: 60040699/0001-19
 I.E.: 244.342.283.119
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 Avenida Pierre Simon de Laplace, 500 - Quadra F - Lote 3 - Osvaldo Cruz - São Paulo - SP - CEP 05.567-77
 Technopark - Campinas - SP - Brasil - CEP 13069-320
 Telefone: + 55 19 3765-9900
 E-mail: gmrreis@gmrreis.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. Téc. Legalmente Habilitado: Geraldo M. dos Reis Jr.
 CREA / SP: 0682127536

Image 1: 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

ACCESS FIT is sold individually, for single use, sterile and presented in 4 packaging levels, described below:

ACCESS FIT is packaged in double surgical grade paper, constituting the primary and secondary packaging containing a label and a sensitive ETO sterilization indicator. 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 heat-shrinkable polyolefin film, constituting the product's quaternary packaging. The product is accompanied by 5 traceability labels and a manual, image 2, on how the user can obtain the product's Instructions for Use, in non-printed format, at no additional cost, including shipping. This information is included in 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	
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.	
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	

Image 2: Manual that comes with the product.

6.4 Sterilization Method

ACCESS FIT is supplied sterile, being sterilized by ethylene oxide (ETO) in accordance with ISO 11135, and must be kept in its original packaging until use, following hospital medical aseptic procedures. 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, meaning that the product will not perform as intended for its intended use, which may pose 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

ACCESS FIT must be stored, handled and transported in such a way as to prevent any damage or alteration to its characteristics and packaging.

ACCESS FIT 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 user's safety.

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

ACCESS FIT must be handled exclusively by medical and hospital professionals, duly trained, qualified and familiar with the technique and procedures involved.

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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		

7. Restrictions on reuse and reprocessing

Reprocessing of ACCESS FIT is not permitted, even if it appears to be in perfect condition, as the product may lose its physical and mechanical properties, not performing as expected for its intended use, which may put the health of patients and staff at risk. health establishment professionals.

8. Specific guidelines for reporting adverse events and technical complaints

If the Access Fit 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.



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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.

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Operating permit – AFE nº 1.02.477 - 0

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Geraldo Marins dos Reis Júnior

CREA – SP nº 0682127536

GM dos Reis Indústria e Comércio Ltda.

Revisions History

Rev. 00 de 2024 – Initial