

1 General Product Identification Information

Single-use, sterile product – sterilized by ethylene oxide

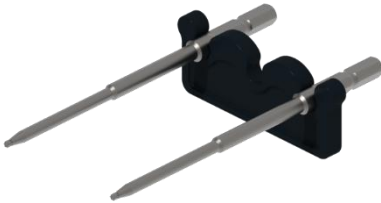
Forbidden to reuse

Product shelf life: 3 years

Technical name: Orthopedic Implant Instruments

Trade name: Sterile screw removal kit – GMReis

1.1 Component Relationship

CODE	Product Description	SPECIFIC USE INDICATION	RAW MATERIAL	GRAPHIC IMAGE
353-1000	Sterile screw removal kit – HE2.0/2.5	Removal of Ø2.7 and Ø3.5 screws – Hexagonal	ASTM F899 Stainless Steel	
353-2000	Sterile screw removal kit – HE3.5	Removal of Ø4.5 and Ø5.0 screws – Hexagonal	ASTM F899 Stainless Steel	
353-3000	Sterile screw removal kit – T4/T6	Removal of Ø1.3, Ø1.5 and Ø2.0 screws	ASTM F899 Stainless Steel	
353-4000	Sterile screw removal kit – T6/T7	Removal of Ø2.0, Ø2.4 and Ø2.7 screws	ASTM F899 Stainless Steel	
353-5000	Sterile screw removal kit – T10/T15	Removal of Ø2.7, Ø3.5 and Ø4.5 screws	ASTM F899 Stainless Steel	

353-6000	Sterile screw removal kit – T20	Removal of Ø4.5 and Ø5.5 screws	ASTM F899 Stainless Steel	
353-7000	Sterile screw removal kit – T15/T25	Removal of screws Ø3.5, Ø5.0	ASTM F899 Stainless Steel	

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 Sterile Kit for screw removal – GMReis, was designed to assist in the removal of screws of various brands, compatible with the models of the kits, the kit consists of sterile keys and extractors used in the removal of screws.

2.2 Indication for use

The Sterile Kit for Screw Removal – GMReis, is indicated to be used in conjunction with the instruments for screw extraction in the removal of screws of various brands, it has in its composition keys and extractors appropriate for the screw connection measurements, performing the indicated function; If used outside the specific indication for use, it may generate risks to the patient and/or procedure, being the responsibility of the professional responsible for the surgical procedure.

2.3 Composition

The instruments of the Sterile Kit for Screw Removal – GMReis, are manufactured in stainless steel according to ASTM F899.

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

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

- Attach the wrench or puller rod to the handle of the screw extraction kit (353-109-1042 or 353-109-1043 – Not subject to this notification);
- Insert the wrench into the screw connection to be removed;
- Make a slight pressure against the screw connection and rotate counterclockwise to remove the screw;



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- d) If the screw connection is damaged, use the extractor and do the same procedure for removal with the wrench.

The instruments are used by surgeons whose surgical technique to be adopted by him is part of their professional training.

The instruments were designed to be connected to the screw fitting and to perform the removal, they should not be used for any other purpose.

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

4.1 Additional information on the procedure before using 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. During the procedure, it is extremely important to use the surgical instrument correctly. Misuse of the surgical instrument may cause corrosion, curvatures, 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, for example, incorrect use can cause breakage and penetration of pieces or components into the patient or someone nearby. If it is damaged, do not reuse it, 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.



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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 instruments of the Sterile Screw Removal Kit – GMReis are contraindicated for any orthopedic surgical procedure other than screw removal.

5 Traceability, form of presentation, cleaning, sterilization, storage, handling and transport

5.1 Marking

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

- GMReis brand logo;
- Product code;
- Product batch.

5.2 Form of presentation of the medical product

The instruments of the Sterile Kit for Screw Removal – GMReis are sold in individual, single-use, sterile form and presented in 4 levels of packaging.

The instruments of the Sterile Screw Removal Kit – GMReis are packaged in a double surgical-grade envelope, image 1, constituting the primary and secondary packages, duly labeled on the back containing a sensitive indicator of sterilization by ETO, where they are supplied separately. 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 is accompanied by: 5 traceability labels and a manual, image 2, on how the user can obtain the product's Instructions for Use, through the non-printed format, at no additional cost, including shipping. 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 em el sitio web: www.gmreis.com.br/produtos/IFU (formato impreso) y siempre será com arreglo a la última version em vigor. aprobado por la Anvisa	 GMREIS Qualidade para Vida
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 em 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 em el etiquetad	

Image 2: Manual that comes with the product.

5.3 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.



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AUT. MS. 1.02.447.0
CNPJ: 60040599/0001-19
I.E.: 244.342.283.119
Razão Social: G.M. DOS REIS INDUSTRIA E COMERCIO LTDA
Avenida Pierre Simon de Laplace, 600 - Quadra F - Lote 3 - Os 9677 -
Technopark - Campinas - SP - Brasil - CEP 13069-320
Telefax: + 55 19 3765-9900
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 3: Traceability label

5.4 Sterilization method

The instruments of the Sterile Kit for Screw Removal – GMReis are supplied sterile, being sterilized by ethylene oxide (ETO) according to ISO 11135, and must be kept in their original packaging until the moment of use, following the hospital medical asepsis procedures. The product is for single use, and should not be resterilized, as this carries 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.

5.5 Validity

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

5.6 Handling, conservation, storage and transport

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

The medical product 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.

It should be preserved and stored in its original packaging, until the moment of use, in a clean, dry, ventilated environment, protected from sunlight, free of contaminating substances (acid and organic vapors), and with temperature and humidity control.

The handling and storage of the product must be done exclusively by professionals in the medical-hospital area, duly trained, qualified and familiar with the technique and procedures involved.

The effects of vibration, shocks, faulty seating, improper stacking and temperature above 45 °C during transport should be avoided.

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

5.7 Labeling Symbology

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

Table 03: Labeling Symbology			
SYMBOLS	DESCRIPTIONS	SYMBOLS	DESCRIPTIONS
	Date of Manufacture		Caution
	Manufacturer		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		

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 instruments of the Sterile Screw Removal Kit – GMReis present a specific unpredictable risk, are out of their specifications or are 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**



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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

Phone: (0XX19) 3765-9900 / Fax: (0XX19) 3003-9111

Anvisa Registration: 10247709021

Qualified Technical and Legal Responsible:

Geraldo Marins dos Reis Júnior

CREA – SP nº 0682127536

GM dos Reis Indústria e Comércio Ltda.

Revision History

Rev. 00 of 16/02/2026 – Initial Process