



INSTRUCTION FOR USE

Versalock Foot Compression Plate System

Sheet:

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3. INSTRUCTIONS FOR USE

3.1. General Product Identification Information

Single-use product.

Non-sterile – sterilize before use as per Sterilization Method.

Reprocessing prohibited.

3.1.1. Information necessary for the user to identify the product and its content

3.1.1.a. Technical Name: Orthopedic fastening systems and associated devices

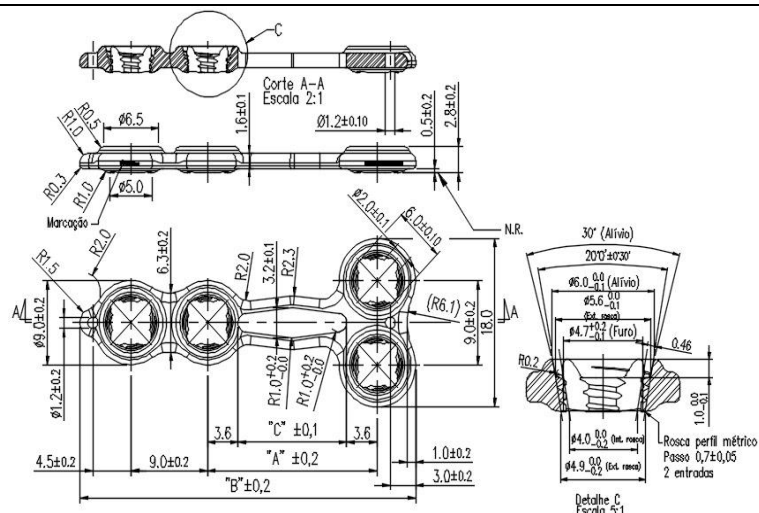
3.1.1.b. Trade Name: Versalock Foot Compression Plate System

3.1.1.c. List of implantable components that make up the product family, with graphic information: drawings, descriptions, dimensional characteristics, tolerances, components, and raw material technical standard for each model, and this information allows viewing the products as they will be delivered for use. Table 1.

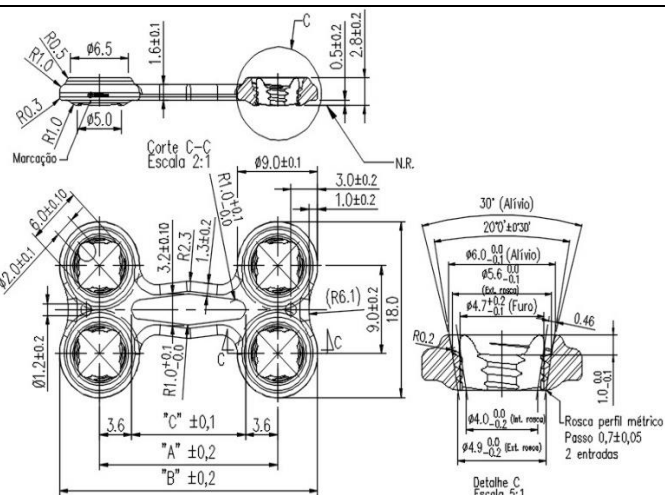
TECNICAL DRAWING

CODE	PRODUCT DESCRIPTION	"A"	"B"	"C"
329-01-15AI	VERSALOCK POLYAXIAL COMPRESSION PLATE 2 HOLES 15.0mm	15.0	27.0	7.8
329-01-20AI	VERSALOCK POLYAXIAL COMPRESSION PLATE 2 HOLES 20.0mm	20.0	32.0	12.8
329-01-25AI	VERSALOCK POLYAXIAL COMPRESSION PLATE 2 HOLES 25.0mm	25.0	37.0	17.8
329-01-30AI	VERSALOCK POLYAXIAL COMPRESSION PLATE 2 HOLES 30.0mm	30.0	42.0	22.8

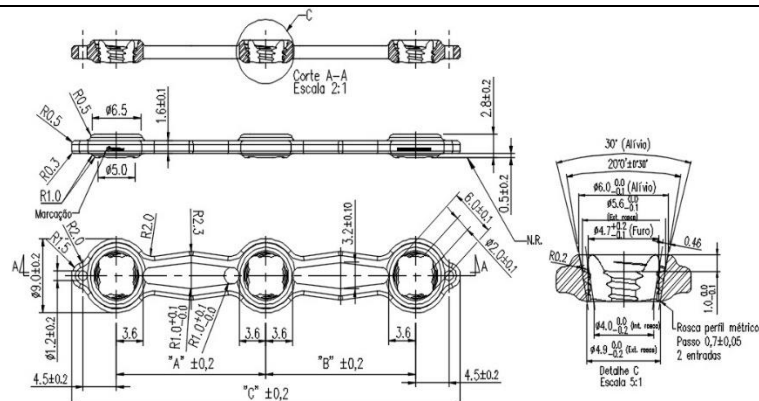
CODE	PRODUCT DESCRIPTION	"A"	"B"	"C"
329-02-20AI	VERSALOCK POLYAXIAL COMPRESSION PLATE T 3 HOLES 20.0mm	20.0	30.5	12.8
329-02-25AI	VERSALOCK POLYAXIAL COMPRESSION PLATE T 3 HOLES 25.0mm	25.0	35.5	17.8
329-02-30AI	VERSALOCK POLYAXIAL COMPRESSION PLATE T 3 HOLES 30.0mm	30.0	40.5	22.8



CODE	PRODUCT DESCRIPTION	"A"	"B"	"C"
	VERSALOCK POLYAXIAL COMPRESSION PLATE T EXTENDED 4 HOLES (A)mm	"A"	"B"	"C"
329-03-20AI	VERSALOCK POLYAXIAL COMPRESSION PLATE T EXTENDED 4 HOLES 20.0mm	20.0	39.5	12.8
329-03-25AI	VERSALOCK POLYAXIAL COMPRESSION PLATE T EXTENDED 4 HOLES 25.0mm	25.0	44.5	17.8
329-03-30AI	VERSALOCK POLYAXIAL COMPRESSION PLATE T EXTENDED 4 HOLES 30.0mm	30.0	49.5	22.8

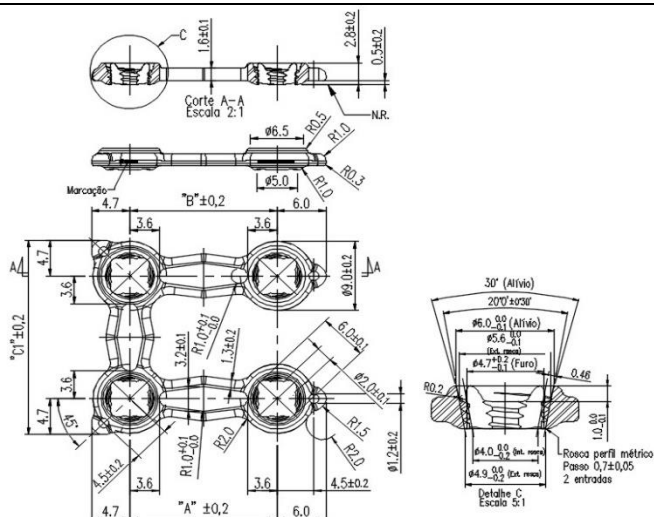


CODE	PRODUCT DESCRIPTION	"A"	"B"	"C"
	VERSALOCK POLYAXIAL COMPRESSION PLATE X 4 HOLES (A)mm	"A"	"B"	"C"
329-04-20AI	VERSALOCK POLYAXIAL COMPRESSION PLATE X 4 HOLES 20.0mm	20.0	29.0	12.8
329-04-25AI	VERSALOCK POLYAXIAL COMPRESSION PLATE X 4 HOLES 25.0mm	25.0	34.0	17.8
329-04-30AI	VERSALOCK POLYAXIAL COMPRESSION PLATE X 4 HOLES 30.0mm	30.0	39.0	22.8

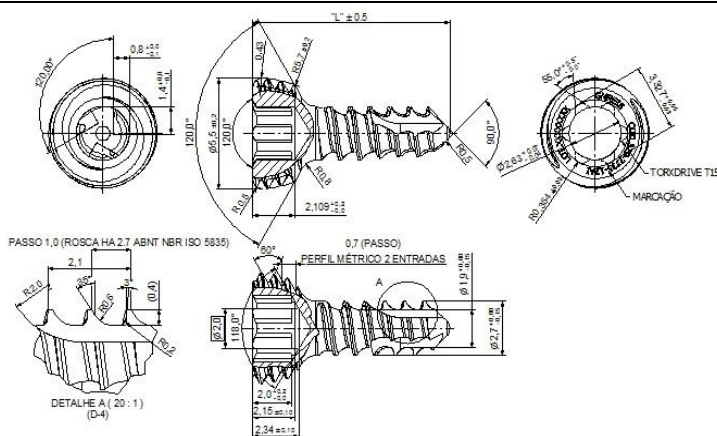


CODE	PRODUCT DESCRIPTION	
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	VERSALOCK POLYAXIAL COMPRESSION PLATE 3 HOLES (A)x(B)mm	"A"	"B"	"C"
329-20-20AI	VERSALOCK POLYAXIAL COMPRESSION PLATE 3 HOLES 20.0x20.0mm	20.0	20.0	52.0
329-20-25AI	VERSALOCK POLYAXIAL COMPRESSION PLATE 3 HOLES 20.0x25.0mm	20.0	25.0	57.0
329-25-25AI	VERSALOCK POLYAXIAL COMPRESSION PLATE 3 HOLES 25.0x25.0mm	25.0	25.0	62.0



CODE	PRODUCT DESCRIPTION	"A"	"B"	"C1"
	VERSALOCK POLYAXIAL COMPRESSION PLATE U 4 HOLES (A)x(B)x(C1)mm			
329-18-18-16AI	VERSALOCK POLYAXIAL COMPRESSION PLATE U 4 HOLES (18.0)x(18.0)x(25.4)mm	18.0	18.0	25.4
329-22-22-19AI	VERSALOCK POLYAXIAL COMPRESSION PLATE U 4 HOLES (22.0)x(22.0)x(28.4)mm	22.0	22.0	28.4
329-30-24-22AI	VERSALOCK POLYAXIAL COMPRESSION PLATE U 4 HOLES (30.0)x(24.0)x(31.4)mm	30.0	24.0	31.4



CODE	PRODUCT DESCRIPTION	"L"
	VERSALOCK TORXDRIVE SCREW 3.5/2.7x(L)mm AI	
329-3527-10AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x10.0mm AI	10.0
329-3527-12AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x12.0mm AI	12.0
329-3527-14AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x14.0mm AI	14.0
329-3527-16AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x16.0mm AI	16.0
329-3527-18AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x18.0mm AI	18.0
329-3527-20AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x20.0mm AI	20.0
329-3527-22AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x22.0mm AI	22.0
329-3527-24AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x24.0mm AI	24.0
329-3527-26AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x26.0mm AI	26.0
329-3527-28AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x28.0mm AI	28.0
329-3527-30AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x30.0mm AI	30.0
329-3527-32AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x32.0mm AI	32.0
329-3527-34AI	VERSALOCK TORXDRIVE SCREW 3.5/2.7x34.0mm AI	34.0

CODE	PRODUCT DESCRIPTION	"L"		"B"
	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x(L)mm Al	12.0		9.1
169-35-12Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x12.0mm Al	12.0		9.1
169-35-14Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x14.0mm Al	14.0		11.1
169-35-16Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x16.0mm Al	16.0		13.1
169-35-18Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x18.0mm Al	18.0		15.1
169-35-20Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x20.0mm Al	20.0		17.1
169-35-22Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x22.0mm Al	22.0		19.1
169-35-24Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x24.0mm Al	24.0		21.1
169-35-26Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x26.0mm Al	26.0		23.1
169-35-28Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x28.0mm Al	28.0		25.1
169-35-30Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x30.0mm Al	30.0		27.1
169-35-32Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x32.0mm Al	32.0		29.1
169-35-34Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x34.0mm Al	34.0		31.1
169-35-35Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x35.0mm Al	35.0		32.1
169-35-36Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x36.0mm Al	36.0		33.1
169-35-38Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x38.0mm Al	38.0		35.1
169-35-40Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x40.0mm Al	40.0		37.1
169-35-42Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x42.0mm Al	42.0		39.1
169-35-44Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x44.0mm Al	44.0		41.1
169-35-45Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x45.0mm Al	45.0		42.1
169-35-46Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x46.0mm Al	46.0		43.1
169-35-48Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x48.0mm Al	48.0		45.1
169-35-50Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x50.0mm Al	50.0		47.1
169-35-52Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x52.0mm Al	52.0		49.1
169-35-55Al	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x55.0mm Al	55.0		52.1

169-35-58AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x58.0mm Al	58.0	55.1
169-35-60AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x60.0mm Al	60.0	57.1
169-35-62AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x62.0mm Al	62.0	59.1
169-35-65AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x65.0mm Al	65.0	62.1
169-35-70AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x70.0mm Al	70.0	67.1
169-35-75AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x75.0mm Al	75.0	72.1
169-35-80AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x80.0mm Al	80.0	77.1
169-35-85AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x85.0mm Al	85.0	82.1
169-35-90AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x90.0mm Al	90.0	87.1
169-35-95AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x95.0mm Al	95.0	92.1
169-35-100AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x100.0mm Al	100.0	97.1
169-35-105AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x105.0mm Al	105.0	102.1
169-35-110AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x110.0mm Al	110.0	107.1
169-35-115AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x115.0mm Al	115.0	112.1
169-35-120AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x120.0mm Al	120.0	117.1
169-35-125AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x125.0mm Al	125.0	122.1
169-35-130AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x130.0mm Al	130.0	127.1
169-35-135AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x135.0mm Al	135.0	132.1
169-35-140AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x140.0mm Al	140.0	137.1
169-35-145AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x145.0mm Al	145.0	142.1
169-35-150AI	VERSALOCK TORXDRIVE LOCKING SCREW (AV) Ø3.5x150.0mm Al	150.0	147.1

3.1.1.d. Description of the physical principle and basics of the technology, application for operation, and action

The Versalock Foot Compression Plate System is a locking system with variable screw fastening angle for foot bone synthesis. The physical principle is based on rigid fastening, simulating an internal fastener where the screws feature a specific thread profile at the head, which, when fastened with suitable instruments, allows the surgeon to fasten using a variable angle of $\pm 15^\circ$ at the threaded hole of the plate, forming an imaginary cone, as shown below.

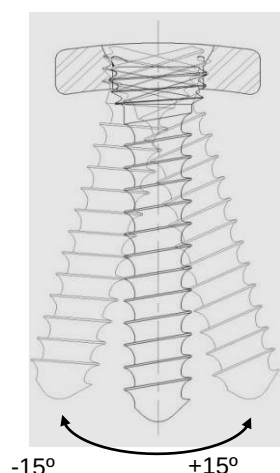


Figure: Illustration of the angle variation at the plate hole.

3.1.1.e. Ancillary components necessary for product deployment (not subject of this registration)

There is not.

3.1.1.f. Technical specification of the raw material used to manufacture the product

The implants of the Versalock Foot Compression Plate System are manufactured from the following material:

Plates:

Stainless Steel Sheet Status: cold-worked

Standard: ASTM F139 "Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants".

Screws:

Round Stainless Steel Bar Status: cold-worked

Standard: ASTM F138 "Standard Specification for Wrought 18 Chromium-14Nickel- 2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants".

3.1.1.g. Marking

Implantable components are identified through laser marking, per ABNT NBR 15165, with the following information:

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

The laser marking site on each product is indicated by the letter "M in all drawings provided in Table 1.

3.1.1.h. Product Traceability Procedure

Product identification and traceability are ensured through a set of 5 stickers provided in the packaging (see label illustration below), along with the Instructions for Use and the implant, providing information about the product, such as name, model, P/N, lot, product registration, and manufacturer ID. This way, taking the reverse path is possible and reach production, raw materials, suppliers, and other quality control items defined in the GMReis Quality System. Traceability labels should be attached at the following spots:

- Label No. 1 must necessarily be attached to the patient's clinical record;
- Label No. 2, on the report delivered to the patient;
- Label No. 3, on the invoice that generates the charge to the paying source;
- Label No. 4, available for supplier control (distribution history record);
- Label No. 5, available for the surgeon's control.



AUT: MS: 1.02.477.0
 CNPJ: 00.540.599/0001-19
 I.E.: 244.342.283-119
 Razão Social: G.M. dos Reis Int. e Com. Ltda
 Av. Paulo Simon de Laplace, 600, Lote 3 Quadra F
 CEP: 13069-329 - Campinas/SP - Condomínio Tênis Park
 Telefone: +55 19 3765-9600
 E-mail: sac@gmreis.com.br

Afixe nos Prontuários / Attach to the Records

NOME TÉCNICO / TECHNICAL NAME:
Sistema de Fixação Rígida de Placas Especiais para Osteossíntese

NOME COMERCIAL / COMMERCIAL NAME:
Sistema de Placas de Compressão Versalock para pé

Modelo / Model: XXXXX

Código / Code: XXXXX

Lote / Lot: XXXXX

*REGISTRO ANVISA N.º:
Resp. Téc. Legalmente Habilitado: Geraldo M. dos Reis Jr.
CREA / SP: 0682127536

Figure: Traceability label.

The medical team and the hospital (the depositories of the patient's details and records) are responsible for attaching the label to the surgery description sheet or a 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 traceability adhesive labels.

3.1.1.i. Product presentation form

Individual presentation form

The implantable components are supplied non-sterile, duly identified, i.e., laser marked with their part number, lot number, and the logo of GMReis.

It is an open system, with the commercial presentation form packaged in individual plastic packages, duly labeled on the back, where the components are supplied separately. The product includes: 5 traceability labels and a manual on how the user can obtain the Instructions for Use of the product, in the non-hardcopy format, at no additional cost, including shipping. This information is compatible with the product labeling.



FRONT



BACK

Figure: Product packaging, front and back, with label.

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	 GMREIS Qualidade para Vida
No campo de busca, procure pelo nº do Registro da 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 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 labelling	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

Figure: Manual that comes with the product.

The supplied templates and the marking site are described in the item in Table 1. The product should be sterilized per item "Sterilization Method".

3.1.1.j. Technical specifications of the packaging

Plastic packaging, in polyethylene (tubular structure or envelope), 75 mm wide x 250 mm long.

3.1.2. Handling, conservation, storage, and transport

The hospital is responsible for the steps of handling, conservation, and storage of the products as of receipt, and must ensure that the manufacturer's recommendations are followed, and that the product keeps the original characteristics as defined.

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

A medical product must be handled with great care, in order to avoid sudden impact, falls, and other risks and/or imperfections that could affect its quality and the user's safety.

It should be conserved and stored in its original packaging or in specific surgical boxes until usage time, with all due care expected from the medical-hospital area, in a clean, dry, and ventilated environment, protected from sunlight and free of contaminating substances (acidic and organic vapors), and with the recommended temperature ($\leq 40^{\circ}\text{C}$) and humidity ($\leq 70\% \text{ RH}$) controls.

The product should be handled only by professionals in the medical-hospital industry, duly trained, qualified, and familiar with the technique and procedures involved.

The effects of vibration, impact, faulty seating, and improper stacking during transport should be avoided.

Storage out of compliance with such conditions may pose risks to the procedure and the patient.

3.1.3. Instructions for the correct use of the product, and training indication**3.1.3.1. Instruction for correct use**

1. Surgical planning, determining which plate is to be used and the implantation zone;
2. Make the surgical incision, and:
 - a. Perform the corrective osteotomy; or
 - b. prepare/decorticate the articular surfaces of the joint to be subjected to arthrodesis;
3. Temporarily fasten the joint (or the osteotomy) by using guide wire(s), already aiming at appropriate anatomical positioning and compression;
4. Place the chosen compression plate and pre-fasten it using a guide wire;
5. Define the diameter of the screws to be implanted together with the plates, and, using the appropriate guides and drills, drill the bone;
6. Measure the depth of the holes made and, using the appropriate instruments, implant the Versalock Screws;
7. Using suitable instruments, use the upper hollow oblong of the plate to compress the joint or osteotomy;
8. Run a final radiological check to assess the positioning of the implants and the final result of the compression;
9. Close the incision.

The time during which this care should be maintained depends on the specific characteristics of each procedure, must be carefully defined by the attending surgeon. Likewise, postoperative care and rehabilitation will depend on numerous variables that cannot be outlined in this document, and which are the absolute responsibility of the multidisciplinary team in charge of the patient.

3.1.3.2. Training indication

Only qualified surgeons trained in orthopedic procedures.

Note 1: The surgeon should be aware of all recommendations listed in the “Instructions for Use” of the product and other information included on the label.

3.1.4. Precautions, restrictions, warnings, special care, clarification on product use, storage, and transport

3.1.4.1. General information

- Single-use product;
- Product supplied non-sterile - sterilize before use according to the recommended “Sterilization Method”; and
- The product should not be reprocessed.

3.1.4.2. Warnings and restrictions regarding the correct choice of implant

The correct choice of implants is of paramount importance. Successful bone consolidation is directly related to the correct choice of the features (model, dimension, etc.) of the implant to be used. The size and shape of bone structures are limiting factors when choosing implants. Metallic implants cannot withstand activity and load levels equivalent to that of natural bones. Always follow the instructions for use of the product.

3.1.4.3. Restrictions on the load on the product

These implants are designed to withstand loads distributed over their surface, when implanted for stabilization of a specific bone structure, and may break while complete bone consolidation does not occur.

Shaping performed on the material during implantation may compromise its mechanical features, which can lead to failure or breakage due to early fatigue.

Using implants for internal fastening allows the surgeon to fasten bone fragments in the correct anatomical position. Implants allow early mobility for patients, but limited to movements without load until the surgeon confirms the fracture healing through X-rays, which usually occurs within ninety (90) days after surgery.

Implants are designed to aid the natural healing process but are not intended to replace anatomical structures or support body weight in the presence of incomplete healing.

The time during which this care should be maintained depends on the specific characteristics of each procedure, should be carefully defined by the attending surgeon. Likewise, postoperative care and rehabilitation will depend on numerous variables that cannot be outlined in this document, and which are the absolute responsibility of the multidisciplinary team in charge of the patient

After ninety (90) days, if complete bone healing does not occur, the product may break due to fatigue, become loose, and/or migrate.

While the load is not completely released, the patient should follow the medical recommendations.

3.1.4.4. Instructions for the patient

The patient should be warned about the limits of his/her initial activities and about his/her rehabilitation, to protect the surgery performed by the attending surgeon.

Excessive initial activity and trauma may affect the implant positioning, which may lead to migration and early wear of the implant or its breaking, impacting the supporting bone structure, making the revision procedure earlier and more difficult.

The patient should be warned about the risks of the surgery and undesirable side or secondary effects, and that the reconstruction performed with the implant will not provide the same characteristics of the natural tissue that was reconstructed, and that the implant may fail as a result of abnormal physical activities, trauma, or degenerative diseases and other diseases.

The patient should be informed that the implant can be replaced whenever the surgeon deems it necessary. The patient should be warned by the attending surgeon to wear appropriate external support until the fracture is completely healed, as well as to restrict physical activity that puts the implant at risk or that allows movements at the fracture focus, delaying bone healing.

It is important for the patient to be aware that the useful life of the implant is ninety (90) days, and s/he should be warned that if bone does not heal during this period, the implants may become loose or broken, especially if the postoperative recommendations are not followed, excess load is applied during physical therapy, and/or in case of poor positioning of the implant, accidents, and other causes.

Patients who are smokers, diabetics, with metabolic disorders and/or who use anabolic steroids, or who are taking any medications capable of compromising healing, and/or who have other diseases that could delay bone consolidation should be informed that bone healing may not occur within the expected 90-day period and that implants may become loose or break, and that a second surgery may be required to remedy the side effects. If the patient has an accident, s/he must be advised that the implant may deform, break, become loose, and/or migrate.

The attending surgeon is responsible for making postoperative recommendations and follow the patient's clinical and radiological evolution.

The patient should be made aware that failure to observe the postoperative recommendations may lead to treatment failure and that the implant may undergo deformation, migration, loosening, and/or breakage.

The patient should be informed that, although the raw material used to manufacture the implant is known to be biocompatible, other side effects or adverse reactions may occur in more sensitive patients, such as:

- Sensitivity to the material;
- Allergic reactions;
- Bone deformity at the implantation site; or
- Incomplete bone healing.

3.1.4.5. Conformation limit (shaping)

GMReis does not recommend shaping Versalock Foot Compression Plate System products.

3.1.4.6. Features of bone support suitable for implantation

If the bone failure requires bone support, the surgeon is responsible for defining the type and amount of bone graft to be used.

3.1.4.7 Warning regarding the surface condition of the product that restricts its use

Plates and screws should not display any clear surface abnormalities, such as scratches, flaws, dirt, or other defects; if any surface abnormalities are evident, the plates must be rendered unusable and discarded per the Disposal Procedure.

3.1.4.8. Warning associated with a component falling

If any implantable component falls or shows any kind of damage, it should be rendered unusable and discarded per the Disposal Procedure.

3.1.4.9. Factors that can lead the implant to potentially break, become loose or migrating, which should be informed to the patient

The main factors that – alone or in combination – can lead to early failure (breakage, loosening or migration) of the implant are listed below.

- Non-compliance with the postoperative recommendations;
- Metabolic disorders;
- Diabetes;
- Smoking;
- Intake of medications that may affect the successful bone healing;
- Patients who have taken or currently take anabolic steroids;
- Patient's accident (e.g. falls, car accidents, etc.)
- Pseudarthrosis;
- Delayed bone healing;
- Faulty surgical technique;
- Improper choice of implant;
- Early load release;
- Failure to use external orthoses, when recommended;
- Excess load or inadequate physical therapy activity;
- Osteoporosis;
- Intense physical activity, and
- Physical activity before release by the surgeon.

3.1.4.10. Procedure related to disposal ensuring that the product is rendered unusable

Implants that, for some reason, were not used during the surgical procedure and whose packaging was opened, damaged and/or have fallen cannot be reused and/or re-sterilized and should be discarded at the hospital per the medical-hospital procedure and/or local regulations, or even per the instructions of the Hospital Infection Control Committee - HICC.

The methods and procedures for disposing of medical products should ensure its complete de-characterization, preventing any possibility of reuse. The de-characterization of a medical product is the sole responsibility of the hospital, as well as the methods and procedures used for disposal.

Deforming the products with molders or twistors is recommended until the product becomes clearly unfit for use, ensuring that the product cannot be used or improperly reused.

3.1.4.11. Removal and handling of implants removed from patients for analysis

When the implant is explanted from the patient and requires submission for analysis, proceed per NBR ISO 12891-1:2011 "Removal and Analysis of Surgical Implants – Part 1 – Removal and Handling", as instructed below:

Implants – and where applicable, adjacent tissue samples – should preferably be removed in a manner that causes minimal damage to both the tissue and implant. It is especially important that functional surfaces such as prosthetic joint surfaces and fractured implant surfaces are protected.

Also, listing the fractured parts of the implant and other components removed is extremely important, making their positioning at the implantation site clear.

The most important part of a surgical implant removal is preventing damage that could lead to a useless scientific examination. For proper scientific examination, the implant must be preserved in a state as close as possible to that in which it existed at the time of removal from the patient. Consequently, care should be taken during the handling, storage, and transport of removed implants, to ensure that no damage or change occurs to the surfaces to be analyzed.

The same precautions must be taken for instruments that fail during use.

The removed implants must undergo a cleaning and disinfection process. Subsequently, they must be separately packed in plastic bags or plastic/glass containers and labeled. The packaging should minimize the possibility of breaks, surface damage, and potential contamination of the implant by the environment. The labeling of products to be sent for analysis should ensure their accurate identification, and the NBR ISO 12891-1:2011 standard recommends using non-removable labels (which tear if removal is attempted).

For an accurate assessment of the cause of product failure, pre- and post-operative X-Rays and checking the implant failure must necessarily be submitted together with the material intended for analysis.



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3.2. Indications, purposes, or intended use of the product

3.2.1. Indicated use

The surgeon in charge of the procedure is responsible for selecting the size of the implantable component that is most appropriate for use, which should be done based on the preoperative radiological study and the correct indication for use.

The correct implant selection is extremely important, considering the biomechanical aspects, and the size and shape of the bone structure to be treated, which corresponds to the size and model of the selected implant.

The success of bone consolidation is related to the correct selection of the implant.

Table below, provides the indications of the plates of the Versalock Foot Compression Plate System that should be used with each plate.

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SURGICAL INDICATION TABLE FOR VERSALOCK POLYAXIAL COMPRESSION PLATES AND COMPATIBILITY WITH VERSALOCK TORXDRIVE SCREWS	Monocortical or bicortical osteotomies of the forefoot	Midfoot and hindfoot osteotomies	Akin's Osteotomy	Hallux MTF arthrodesis and osteotomies for Hallux Valgus correction	Lisfranc arthrodesis	Tarsometatarsal arthrodesis - TMT					Intercuneiform arthrodesis	Cuneonavicular arthrodesis	Talonavicular arthrodesis	Calcaneocuboid arthrodesis	Torxdrive Versalock Ø2.5/2.7 Al screw 	Torxdrive Versalock screw (AV) Ø3.5 Al 
						1	2	3	4	5						
 329-01-15AJ Versalock Polyaxial Compression Plate, 2 Holes, 15.0 mm 329-01-20AJ Versalock Polyaxial Compression Plate, 2 Holes, 20.0 mm 329-01-25AJ Versalock Polyaxial Compression Plate, 2 Holes, 25.0 mm 329-01-30AJ Versalock Polyaxial Compression Plate, 2 Holes, 30.0 mm	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
 329-20-20AJ Versalock Polyaxial Compression Plate, 3 Holes, 20.0 x 20.0 mm 329-20-25AJ Versalock Polyaxial Compression Plate, 3 Holes, 20.0 x 25.0 mm 329-20-25AJ Versalock Polyaxial Compression Plate, 3 Holes, 20.0 x 25.0 mm				X	X	X	X	X	X	X	X	X	X	X	X	X
 329-04-20AJ Versalock X Polyaxial Compression Plate, 4 Holes, 20.0 mm 329-04-25AJ Versalock X Polyaxial Compression Plate, 4 Holes, 25.0 mm 329-04-30AJ Versalock X Polyaxial Compression Plate, 4 Holes, 30.0 mm		X		X	X	X	X	X	X		X	X	X	X	X	X
 329-04-20AJ Versalock T Polyaxial Compression Plate, 4 Holes, 20.0 mm 329-04-25AJ Versalock T Polyaxial Compression Plate, 4 Holes, 25.0 mm 329-04-30AJ Versalock T Polyaxial Compression Plate, 4 Holes, 30.0 mm	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X
 329-03-20AJ Versalock T Extended Polyaxial Compression Plate, 4 Holes, 20.0 mm 329-03-25AJ Versalock T Extended Polyaxial Compression Plate, 4 Holes, 25.0 mm 329-03-30AJ Versalock T Extended Polyaxial Compression Plate, 4 Holes, 30.0 mm	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X
 329-18-18-16AJ Versalock U Polyaxial Compression Plate + Holes (18.0) x (18.0) x (25.4) mm 329-22-22-19AJ Versalock U Polyaxial Compression Plate + Holes (22.0) x (22.0) x (28.4) mm 329-30-24-22AJ Versalock U Polyaxial Compression Plate + Holes (30.0) x (24.0) x (35.4) mm					X	X	X	X			X	X		X	X	X

3.2.2. Undesirable secondary or side effects**3.2.2.a. Efeitos Secundários ou Colaterais Indesejáveis**

The products in the Versalock Foot Compression Plate System are manufactured with raw materials of recognized biomedical uses, which adhere to the requirements of the following international standard:

- *ASTM F139 “Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants”,* for the manufacture of plates; and
- *ASTM F138 “Standard Specification for Wrought ¹⁸Chromium-¹⁴Nickel-^{2.5}Molybdenum Stainless Steel Bar and Wire for Surgical Implants”,* for the manufacture of screws.

The chemical, metallographic, and mechanical requirements of the material standards are used as a criterion to ensure the product's purity and biomechanical performance, characterizing it as suitable for implantation in the human body. It should be noted, however, that no surgical implant material is shown to be completely free of adverse reactions in the human body, and that an acceptable level of biological response can be expected when the material is used for appropriate applications.

Thus, the product may lead to some undesirable side effects caused by the biomaterial:

- Sensitivity to the metal or allergic reaction to a foreign body;
- Pain, discomfort, and abnormal feeling due to the incorrect use and indication of the implant.

Before implantation, the surgeon should preferably assess any sensitivity of the patient to the use of the biomaterial.

Other undesirable side effects related to the surgical procedure and product placement:

- Consolidation delay or pseudarthrosis, which may lead to loosening or rupture of the implant when bone consolidation does not occur within 90 days after surgery;
- Broken or loose implants because the postoperative rehabilitation guidelines were not followed and/or excessive load during physical therapy and/or incorrect positioning of the implant;
- Limb shortening due to fracture compression or bone resorption;
- Decreased bone density;
- Pain, discomfort, and abnormal feeling due to the presence of the implant;
- Bone necrosis, and;
- Vascular changes and other changes inherent to the surgical procedure.

Note 1: Patients who smoke (smokers) have greater difficulties in achieving bone consolidation, consequently there are greater chances of occurrence of deformation, rupture or loosening of the implants.

Note 2: Other interventions may be necessary to repair side effects

3.2.2.b. Contraindications

Patients with any clinical condition listed below should not undergo procedures in which implants of the Versalock Foot Compression Plate System are used:

- Active infection or history of recent infection of the local bone or soft tissues;
- Osteometabolic diseases leading to bone mass fragility or reduction;
- Insufficient or poor-quality bone mass;
- Inadequate vascularity at the implant placement site, which may compromise proper blood supply to the implantation site;
- Patients with previously placed implants that may compromise implantation and/or interfere with the product;
- Drug abuse and alcoholism;
- Fever;
- Pregnancy;
- Possibility of conservative treatment;
- Patients without psychological and physiological conditions;
- Patients with inadequate neurovascular, bone or skin status;
- Allergy and/or sensitivity to metals and
- Patients unable to follow recommendations of the physician or the medical team at any time during their treatment.

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

3.3.1. Allowable combinations with other materials

The materials used to manufacture the products are stainless steel, as follows: ASTM F139 “Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants”, for the manufacture of plates, and

ASTM F138 “Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants”, for the manufacture of screws.

The steels in question are highly resistant to corrosion in the physiological environment. Nevertheless, the product cannot be used together with any product from another manufacturer, or any alloy product with a different chemical composition, as this association may lead to chemical incompatibilities (creating galvanic and other types of corrosion), and/or physical, biological, and functional incompatibilities, early fatigue, and potential risks to the patient.

The product should be implanted only with the aid of specific instruments bearing the GMReis brand, as shown in Table below.

Should the surgeon use any improper combination, s/he will be liable for the risks associated with such combination.

3.3.2. 1.a.1. Non-implantable components: Instruments of the Versalock Foot Compression Plate System (NOT ADDRESSED BY THIS REGISTRATION), required for implantation of the product.

To place the Versalock Foot Compression Plate System, the GMReis-brand products listed in table 2 should be used.

Table 2: Instruments of the Versalock Foot Compression Plate System (NOT ADDRESSED BY THIS REGISTRATION)

P/N	PRODUCT DESCRIPTION
169-154	DEPTH GAUGE 10-60mm
223-305	BEADED GUIDE WIRE Ø 1.0 x 10.0 x 100.0 mm
223-306	BEADED GUIDE WIRE Ø 1.0 x 20.0 x 100.0 mm
223-314	CABLE WITH TORQUE LIMITER 1.3Nm
229-106	DRILL Ø2.5x150.0mm
234-27	DRILL Ø2.0x150.0mm
329-102	VERSALOCK DRILL GUIDE +/- 15° STAINLESS STEEL Ø2.0mm
329-103	VERSALOCK DRILL GUIDE +/- 15° STAINLESS STEEL Ø2.5mm
329-104	STRAIGHT 0° STAINLESS STEEL DRILL GUIDE Ø2.0mm
329-105	STRAIGHT 0° STAINLESS STEEL DRILL GUIDE Ø2.5mm
329-107	SCREW WRENCH T15x115.0mm SELF RETAINING
329-108	DISTRACTION TWEEZERS FOR STAINLESS STEEL COMPRESSION PLATES
329-200	PIN BENDER
329-201	PLATE BENDER
329-208	Ø2.0 X 150.0 MM DRILL BIT
329-207	Ø2.5 X 150.0 MM DRILL BIT

The instruments used to implant the products are not the object of this registration, they are not part of the product, and should be purchased separately.

3.3.3. Accessories

The product does not have accessories.

3.5. Useful information to avoid risks arising from implantation

3.5.1. Implantation risk

Although the raw materials used to manufacture the products are biocompatible and standardized per ASTM F139 "Standard Specification for Wrought 18 Chromium-14Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants" and ASTM F138 "Standard Specification for Wrought 18 Chromium-14Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants," the patient may experience sensitivity to the product or an allergic reaction. It is known that, even if a raw material provides the chemical, mechanical, and microstructural requirements determined by standards (which ensures its purity

and biomechanical performance, making it suitable for use as a material for the manufacture of implants), no material can ensure total absence of adverse reactions in the human body.

To avoid further implantation risks, other precautions can be taken, such as:

- Total aseptic condition;
- Previous, intraoperative radiological evaluation;
- Following the instructions for use, and,
- Appropriate selection of the implant type and size based on preoperative radiological planning.

Other implantation risks:

- Surgical indication failure,
- Failure in the surgical technique, and/or,
- Lack of patient cooperation regarding postoperative recommendations.

3.5.2. Evaluation of the implanted product

After implantation, during the intraoperative period, the attending healthcare professional should carry out radiological control to check the correct positioning of the product. The professional in charge is responsible for performing the clinical and radiological reviews after the surgical procedure, at the frequency stipulated by him/her, to check the implant status and the evolution of bone consolidation. If the product is found out of correct positioning, or shows non-compliance, the surgeon is responsible for taking the most appropriate corrective action.

3.5.3. Restrictions and instructions on packaging damage

Under the circumstances described below, the product must be scrapped and disposed of as per the product disposal procedure:

- Packaging sealing zone violated;
- Physical damage on any packaging;
- Unreadable label or ID code, and,
- Expiration date elapsed.

3.5.4. Restrictions on reprocessing

Reprocessing the product is not allowed, even if it appears to be in perfect condition, as the product may lose its physical and mechanical properties, not performing as expected for the intended use, which could jeopardize the health of patients and professionals at healthcare establishments.

3.8. / 3.9. Additional information about the procedure before using the product

When opening the packaging, check the surface condition of the product for deformations, stains, scratches, or any other type of surface alteration or defect; then forward the product for sterilization, following the recommendations as indicated in item "Sterilization Method."



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The product packaging should be discarded according to medical-hospital procedure and/or local regulations, or even per instructions from the Hospital Infection Control Committee - HICC.

3.8. / 3.9. Sterilization Method

The products are supplied non-sterile, and the hospital is responsible for sterilization before surgery, using the method it deems most convenient and safe, in compliance with the technical standards and current regulations from ANVISA and the Ministry of Health. The sterilization procedures, as well as the quality and training of the personnel involved in this process, are the sole responsibility of the healthcare provider.

GMReis recommends that products should be sterilized by the following method:

Type: moist heat

Cycle: gravitational

Temperature: 121°C (250°F)

Exposure time: 60 minutes

Additional information regarding sterilization is provided in ABNT NBR ISO 17665-1- "Sterilization of Healthcare Products – Steam. Part 1: Requirements for the development, validation, and routine control of sterilization processes for healthcare products."

3.14. Specific guidelines for physicians regarding the reporting of adverse events

If the product presents adverse events not reported in the instructions for use or technical complaints are made about the product, the physician should immediately contact the manufacturer through GM Reis Customer Service Center (SAC), in addition to notifying the competent health authority, ANVISA, via e-mail: tecnovigilancia@anvisa.gov.br. More information can be found in the National Health Surveillance Notifications System – NOTIVISA (web: <http://www.anvisa.gov.br/hotsite/notivisa/apresenta.htm>). To ensure product traceability, the physician must proceed per the "product traceability procedure". Product traceability is ensured through all 5 traceability labels provided inside the package, together with the Instructions for Use, as described in item "Product Traceability Procedure".

3.17. Customer complaints

If the medical product poses a specific, unpredictable risk, is out of specification, or is creating any dissatisfaction, please 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-compliance to the following address: Avenida Pierre Simon de La Place, 600, Lote 3, Quadra F, Quarteirão 9677 – TechnoPark – CEP: 13069-320, Campinas – SP, Brazil, or call directly Tel.: (0XX19) 3765-9900 / Fax.: (0XX19) 3765-9111 / E-mail: sac@gmreis.com.br.

3.18. Labeling Symbology

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

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Data de fabricação		Produto de Uso único "Não reutilize"
	Prazo de Validade		Informações adicionais "Ver instruções de uso"
	Manter seco		Manter ao abrigo da luz

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 verified in the search field by trade name and registration number in Anvisa, described on the product packaging label. The Instructions for Use made available will always be in accordance with the latest version in effect. If there is interest from the user, the Instructions for Use may be made available in printed format, at no additional cost. Request for free by email: sac@gmreis.com.br.

G. M. dos Reis Indústria e Comércio Ltda.

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