

Section 21 - Instructions for Use

INSTRUCTIONS FOR USE

Versalock Rib and Sternum Plates System.

DEVICE DESCRIPTION

The Versalock Rib and Sternum Plates System is indicated for the stabilization and rigid fixation of chest wall fractures, including sternal reconstruction processes, trauma and/or planned osteotomies. The physical principle is based on rigid fixation, where the screws have a specific thread profile in their head, which, when fixed, allows the surgeon to fix it with a variable angle of $\pm 15^\circ$ in the threaded hole of the plate. The system also allows fixation with non-threaded head screws when the surgeon so desires. The devices are presented in Titanium Alloy according to the standard ASTM F136 and Pure Titanium According to ASTM F67.

HOW SUPPLIED

They are found in a variety of diameters to meet the range of anatomies of the patients. The subject devices could be provided in sterile condition sterilized by Ethylene Oxide or non-sterile condition to end user, the non-sterile version must be cleaned, and steam sterilized before use.

INDICATIONS FOR USE

The Versalock Rib and Sternum Plates System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy, sternal reconstructive surgical procedures, rib and sternum fractures, fusions and osteotomies.

CONTRAINDICATIONS

Contraindications are listed below, but are not limited to:

- Active infection or history of recent infection of the bone tissue or local soft parts;
- Osteometabolic diseases that cause weakness or reduction of bone mass;
- Insufficient/poor quality bone mass;
- Inadequate vascularization at or near the implantation site could compromise the adequate blood supply;
- Patients with existing implants may compromise implantation and/or interfere with the product;
- Drug abuse and alcoholism;
- Fever;
- Pregnancy;
- Allergy and/or sensitivity to metal, and
- Patients who are incapacitated and/or uncooperative during all the treatment phases.

WARNINGS AND PRECAUTIONS

- This device is intended to be used by a trained medical professional.
- Non-sterile implants must undergo both cleaning and sterilization prior to use, according to recommended sterilization method;
- Single-use product, do not reuse, even if it is in perfect condition;
- Detailed instructions on the use and limitations of this device should be given to the patient.
- Surgeons must apply their professional judgment when determining the appropriate sized device based on the specific indication, preferred surgical technique, and patient history.
- The plates are pre-contoured to fit the geometry of the bones. Anatomic rib plates provide reliable fixation and simplify the surgical procedure by eliminating the need for extensive intraoperative plate contouring. If additional shaping is necessary, you can use Shaping Pliers or the Rib Plate Shaper, which has the appropriate profile for shaping the plate. In both cases, it is crucial to avoid sharp

bends, reverse bends and bending at the device screw holes. Avoiding notches or scratches on the plate is equally important. These factors may produce internal stresses, which may become the focal point for eventual breakage of the implant. Using incorrect instrumentation for modeling can weaken the plate, resulting in premature failure such as breakage. Never bend the plate more than necessary to fit the anatomy. It is essential to shape the plate according to the modeling template.

GENERAL INFORMATION - REPROCESSING

Non-Sterile Implants (Single-Use) and Instruments:

- Point of Use Preparation for Reprocessing: Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place devices in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on devices prior to cleaning.
- Cleaning process is the first step in effectively reprocessing devices. Adequate sterilization depends on thoroughness of cleaning.
- Cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.
- It is recommended that all new relevant clinical practice guidelines be followed as per the CDC guidance, “Guideline for Disinfection and Sterilization in Healthcare Facilities”.
- It is recommended to rinse the device components with water that meets specifications for AAMI TIR34 “Water for the reprocessing of medical devices” for example, DI/RO water.

Devices are usually supplied in sets and subdivided into trays and cases in which the devices may be arranged by size or in the order needed for a specific surgical procedure and should be used to transportation and storage.

NOTE: Any implant that has not been used, but has become soiled, should be handled according to hospital protocols. Refer to implant product inserts for any specific processing, cleaning, and sterilization instructions for that implant.

The type of water and the recommended water quality levels are considered according to AAMI TIR 34 "Water for reprocessing of medical devices".

Devices Preparation:

- Cleaning, inspection, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Before use, medical devices must be cleaned to ensure that there is no risk to the patient from the transmission of infectious agents and other residues that could become toxic.

Cleaning Instructions for non-sterile devices:

- Devices must be thoroughly cleaned prior to sterilization.
- Disconnect all handles/knobs prior to cleaning.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
- Ensure all moving parts of instruments are cleaned at both extents.
- Handle all products with care. Mishandling may lead to damage and possible improper functioning.
- Thoroughly clean the instruments, trays and inserts using only recommended cleaning solutions.

- Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, replace it with a new piece.

NOTE 1: The information on concentration, temperature, quality water, exposure time and cycles used in the equipment, follow the instructions for use and labels according to products manufacturer.

Manual Cleaning

- In a sink the devices must be thoroughly rinsed in running water to remove excess soil or contaminants.
- Prepare a Prolystica® Steris enzymatic detergent solution according to the label instructions using distilled water at a concentration of 4 mL of detergent per liter of water (4 mL/1L).
- Then, with a brush soaked in the prepared solution, brush the devices until all visible soil has been removed for a minimum of 1 minute. Water temperature between 35°C and 65°C.
- Wash the devices with running water and repeat the brushing process as many times as necessary to thoroughly clean the device.
- Finally, wash the devices with distilled water and dry and protected place.

Preparation of detergent and disinfectant solutions

- Prepare a solution at a concentration of 4 mL of detergent per liter of water (4 mL/1L) of Prolystica® Steris enzymatic detergent using potable water. Water temperature between 35°C and 65°C.
- Prepare another solution at a concentration of 5% neutral detergent according to the label instructions (50 mL of detergent for each liter of water) using potable water. Water temperature between 35°C and 65°C.

- Prepare a disinfectant solution at a concentration of 29.6 mL of disinfectant to 3.78 L of water of Vesta Syde SQ disinfectant according to label instructions using potable water. Water temperature between 35°C and 65°C.

Washing

- Pre-rinse the devices in running water to remove excess of soil or contaminants.
- Then, immerse the devices were in the prepared enzymatic detergent solution for at least 10 minutes.
- After the action time, thoroughly brush the items, until all visible residuals has been removed for a minimum of 1 minute, with the neutral detergent solution.
- Finally, wash them in running water, until all visible residuals has been removed for a minimum of 1 minute, and drain on absorbent paper to remove excess water.

Disinfection

- Immerse the devices in disinfectant solution previous prepared in containers.
- Wait the action time of 10 minutes.
- After the time, wash the devices until all visible residuals has been removed for a minimum of 1 minute, thoroughly with distilled, deionized (DI) or purified (PURW) water;
- With the aid of absorbent paper, dry the devices.

INSPECTION, MAINTENANCE, TESTING

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.
- Visually inspect for completeness, damage and/or excessive wear.
- Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.

GMReis instruments must be inspected after processing and prior to sterilization in order to ensure proper function. Further use is confirmed by the successful inspection of the product. Some point to be inspected are:

- Cleanliness;
- Damage, including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear;
- Proper function, including but not limited to, sharpness of cutting tools, bending of flexible devices, movement of hinges/joints/box locks and moveable features such as handles, ratcheting and couplings and
- Missing or removed (buffed off) part numbers
- Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should not be used.

STERILIZATION/RESTERILIZATION

Implants (non-sterile) and instruments should be autoclave sterilized using the following validated cycle parameters. The hospital is responsible for sterilization before surgery, through the method he finds more convenient and secure, while respecting the technical standards and current sanitary regulations. The sterilization procedures as well as the quality and the training of staff involved in this process is sole responsibility of the health service. GMReis recommends the following validated cycle:

STEAM STERILIZATION CYCLES - FOR NON-STERILE PRESENTATION

Type: humid heat

Cycle: gravitational

Temperature: 121°C (250°F)

Exposure Time: 30 minutes

Minimum Drying Time: 15 – 30 min.

The product must be wrapped with an FDA-cleared wrap.

Additional information regarding sterilization is described in ISO 17665-1- “Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices”.

ETHYLENE OXIDE STERILIZATION - FOR STERILE PRESENTATION

When supplied sterile, the method used is ethylene oxide sterilization, according to ISO 11135, implants must be maintained in its original packaging until the moment of its use.

MRI SAFETY INFORMATION

The Versalock Rib and Sternum Plates has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Versalock Rib and Sternum Plates in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

POTENTIAL ADVERSE EVENTS

- Nonunion or delayed union which may lead to breakage of the implant
- Bending or fracture of the implant
- Metal sensitivity or allergic reaction to a foreign body
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to presence of device
- Nerve damage due to surgical trauma
- Necrosis of bone
- Implant migration

STORAGE

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

The product must be conserved and stored in its original packaging until the moment of use, with the due care of the medical-hospital area, in a clean, dry, airy environment, protected from sunlight and free of contaminating substances (acid and organic vapors), and with controls, recommended, at room temperature.

The handling 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.

SURGICAL TECHNIQUE

1. Perform radiological and clinical evaluation;
2. Position the patient and perform surgical access;
3. Confirm which plate is most suitable for the patient's needs, considering the model (morphology) and dimensions;
4. Reduce the fracture by temporarily securing the fragments with applicable instruments;
5. Position the chosen plate fixing it;
6. Position the guide in the threaded hole of the plate, drill with the appropriate drill and apply the screw with the wrench;
7. Drill with the appropriate drill and at the most appropriate angle for screw application;
8. Measure the hole with the depth gauge;
9. With the wrench accompanied by the torque limiter, apply the screw determined by the measurement, locking it in the plate.
10. Carry out the radiological and functional evaluation (if necessary) to verify the positioning of the implants and the quality of the treatment;
11. Close the surgical incisions.

Consult the complete surgical technique for more information.

IMPLANT REMOVAL

When the implant is explanted from the patient, proceed in accordance with ISO 12891-1 “Removal and Analysis of Surgical Implants – Part 1 – Removal and Handling”, as per the instructions below:

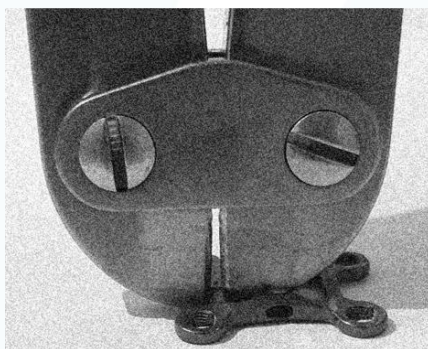
It is recommended that implants, and in applicable cases, adjacent tissue samples, be removed in a manner that causes minimal damage to both tissue and implant. It is especially important that the surfaces of fractured implants are protected.

It is also extremely important to list the fractured parts of the implant and other removed components, making their positioning in the implantation site clear.

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

EMERGENCY RE-ENTRY

Should emergent re-entry be required, the cuttable cross-sections of the plate closing the sternotomy can be easily cut with standard wire cutters.



USER WARNING

These Instructions for Use are available on-line, through the electronic address of the manufacturer: <http://www.gmreis.com.br/produtos/IFU>, and can be checked in the search field by trade name, described on the label of the product packaging. The Instructions for use provided will always be in accordance with the current latest version. If there is interest from the user, the Instructions for Use may be available in printed format, without additional cost. Ask for free by e-mail: sac@gmreis.com.br

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed physician.

FURTHER INFORMATION

If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, directly notify the GM Dos Reis Customer Service. GM Dos Reis Indústria e Comércio Ltda - Pierre Simon de Laplace Avenue, no.600 TECHNOPARK – CEP: 13069-320 – Campinas – SP – BRAZIL or directly notify at Telephone Number:+55 19 3765-9900; E-mail: sac@gmreis.com.br

SYMBOLS GLOSSARY

Non-Sterile			
Symbol	Description	Symbol	Description
	Date of Manufacture		Batch number
	Manufactured by		Caution “see instructions for use”
	Use-by date		Keep away from sunlight
	Keep dry		Do not use if package is damaged
	Prescription use only		Product catalogue number
	Non-sterile		See Package Insert
	Do not reuse		

Sterile			
Symbol	Description	Symbol	Description
	Date of Manufacture		Batch number
	Manufactured by		Caution "see instructions for use"
	Use-by date		Keep away from sunlight
	Keep dry		Do not use if package is damaged
	Prescription use only		Product catalogue number (Reference/Part Number)
	Sterile		See Package Insert
	Do not reuse		

COMPANY NAME / MANUFACTURER NAME:

GM dos Reis Industria e Comercio Ltda.

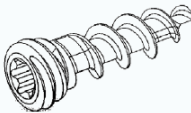
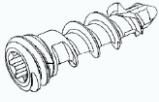
Avenida Pierre Simon de Laplace, no. 600 Lote 3 - Quadra F - Block 9677
 TECHNOPARK – CEP: 13069-320 – Campinas – SP - BRAZIL

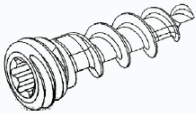
Email: qualidade@gmreis.com.br

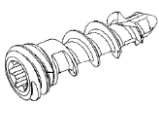
Telephone number: +55 19 37659900

RIB AND STERNUM, Revision: 00, April 2, 2024

NON STERILE PRODUCTS			
Image	Code	Description	Dimension (mm)
	344-01	Versa Rib Plate - 08 Holes	1.6x9x80
	344-02	Anatomical Versalock Rib Plate - 12 Holes	1.6x9x119.35
	344-03	Anatomical Versalock Rib Plate - 16 Holes	1.6x9x158.36
	344-04	Anatomical Versalock Rib Plate - 24 Holes	1.6x9x234
	344-05	Versalock Sternum Plate - 100° - 04 Holes	1.6x10.82x29
	344-06	Quadrilateral Versalock Sternum Plate - 04 Holes	1.6x19x19
	344-07	"H" Versalock Sternum Plate - 08 Holes	1.6x23.5x34
	344-08	"JL" Versalock Sternum Plate - 08 Holes	1.6x26.48x28

	344-11	Double Quadrilateral Wide Versalock Sternum Plate - 12 Holes	1.6x24x54
	344-12	Double Quadrilateral Narrow Versalock Sternum Plate - 12 Holes	1.6x18.5x54
	344-13	Sternum Fixation Versa Plate - 04 Holes	1.6x6x40
	344-14	Sternum Fixation Versa Plate - 08 Holes	1.6x6x65
	344-15	“T” Versalock Sternum And Rib Plate - 40 Holes	1.6x46x177
	344-16	“H” Versalock Sternum Tape Plate - 08 Holes	1.6x24x35
	344-17	Quadrilateral Versalock Sternum Tape Plate - 04 Holes	1.6x20x24
	344-18	“Butterfly” Versalock Sternum Tape Plate - 06 Holes	1.6x26x30
	344-30	Wave Versalock Rib Plate - 22 Holes	1.6x11x117.5
	344-31	Wave Versalock Rib Plate - 28 Holes	1.6x11x149
	344-32	Wave Versalock Rib Plate - 40 Holes	1.6x11x212
	344-24-07-BP	Versalock Rib and Sternum Screw–T7 Self Drilling Ø2.4 x 7.0mm	Ø2.4 x 7.0
	344-24-08-BP	Versalock Rib and Sternum Screw–T7 Self Drilling Ø2.4 x 8.0mm	Ø2.4 x 8.0
	344-24-10-BP	Versalock Rib and Sternum Screw–T7 Self Drilling Ø2.4 x 10.0mm	Ø2.4 x 10.0
	344-24-12-BP	Versalock Rib and Sternum Screw–T7 Self Drilling Ø2.4 x 12.0mm	Ø2.4 x 12.0
	344-24-14-BP	Versalock Rib and Sternum Screw–T7 Self Drilling Ø2.4 x 14.0mm	Ø2.4 x 14.0
	344-24-16-BP	Versalock Rib and Sternum Screw–T7 Self Drilling Ø2.4 x 16.0mm	Ø2.4 x 16.0
	344-24-18-BP	Versalock Rib and Sternum Screw–T7 Self Drilling Ø2.4 x 18.0mm	Ø2.4 x 18.0
	344-24-20-BP	Versalock Rib and Sternum Screw–T7 Self Drilling Ø2.4 x 20.0mm	Ø2.4 x 20.0
	344-27-07-BP	Versalock Rib and Sternum Screw–T7 Self Tapping Ø2.7 x 7.0mm	Ø2.7 x 7.0
	344-27-08-BP	Versalock Rib and Sternum Screw–T7 Self Tapping Ø2.7 x 8.0mm	Ø2.7 x 8.0
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	344-27-14-BP	Versalock Rib and Sternum Screw–T7 Self Tapping Ø2.7 x 14.0mm	Ø2.7 x 14.0
	344-27-16-BP	Versalock Rib and Sternum Screw–T7 Self Tapping Ø2.7 x 16.0mm	Ø2.7 x 16.0
	344-27-18-BP	Versalock Rib and Sternum Screw–T7 Self Tapping Ø2.7 x 18.0mm	Ø2.7 x 18.0
	344-27-20-BP	Versalock Rib and Sternum Screw–T7 Self Tapping Ø2.7 x 20.0mm	Ø2.7 x 20.0

STERILE PRODUCTS			
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	344-01S	Versa Rib Plate - 08 Holes	1.6x9x80
	344-02S	Anatomical Versalock Rib Plate - 12 Holes	1.6x9x119.35
	344-03S	Anatomical Versalock Rib Plate - 16 Holes	1.6x9x158.36
	344-04S	Anatomical Versalock Rib Plate - 24 Holes	1.6x9x234
	344-05S	Versalock Sternum Plate - 100° - 04 Holes	1.6x10.82x29
	344-06S	Quadrilateral Versalock Sternum Plate - 04 Holes	1.6x19x19
	344-07S	“H” Versalock Sternum Plate - 08 Holes	1.6x23.5x34
	344-08S	“JL” Versalock Sternum Plate - 08 Holes	1.6x26.48x28
	344-11S	Double Quadrilateral Wide Versalock Sternum Plate - 12 Holes	1.6x24x54
	344-12S	Double Quadrilateral Narrow Versalock Sternum Plate - 12 Holes	1.6x18.5x54
	344-13S	Sternum Fixation Versa Plate - 04 Holes	1.6x6x40
	344-14S	Sternum Fixation Versa Plate - 08 Holes	1.6x6x65
	344-15S	“T” Versalock Sternum and Rib Plate - 40 Holes	1.6x46x177
	344-16S	“H” Versalock Sternum Tape Plate - 08 Holes	1.6x24x35
	344-17S	Quadrilateral Versalock Sternum Tape Plate - 04 Holes	1.6x20x24
	344-18S	“Butterfly” Versalock Sternum Tape Plate - 06 Holes	1.6x26x30
	344-30S	Wave Versalock Rib Plate - 22 Holes	1.6x11x117.5
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	344-32S	Wave Versalock Rib Plate - 40 Holes	1.6x11x212
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	344-24-12-BPS	Versalock Rib and Sternum Screw-T7 Self Drilling Ø2.4 x 12.0mm	Ø2.4 x 12.0
	344-24-14-BPS	Versalock Rib and Sternum Screw-T7 Self Drilling Ø2.4 x 14.0mm	Ø2.4 x 14.0
	344-24-16-BPS	Versalock Rib and Sternum Screw-T7 Self Drilling Ø2.4 x 16.0mm	Ø2.4 x 16.0

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	344-27-14-BPS	Versalock Rib and Sternum Screw-T7 Self Tapping Ø2.7 x 14.0mm	Ø2.7 x 14.0
	344-27-16-BPS	Versalock Rib and Sternum Screw-T7 Self Tapping Ø2.7 x 16.0mm	Ø2.7 x 16.0
	344-27-18-BPS	Versalock Rib and Sternum Screw-T7 Self Tapping Ø2.7 x 18.0mm	Ø2.7 x 18.0
	344-27-20-BPS	Versalock Rib and Sternum Screw-T7 Self Tapping Ø2.7 x 20.0mm	Ø2.7 x 20.0

MATRIZ | HEADQUARTER

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