

	Premarket Notification 510(k) - FDA	FORM. 02.1 - V	
		Issuance:	19/12/2023
		Revision:	00
		Sheet:	1/13

INSTRUCTIONS FOR USE

Pectus Versa System

GENERAL INFORMATION

- Single-use product, do not reuse, even if it is in perfect condition;
- Non-sterile supplied product;
- Sterilize before use, according to recommended sterilization method;
- Prohibited reprocessing.

INDICATIONS FOR USE

The Pectus Versa System is indicated for the treatment of Pectus Excavatum and other anterior chest wall deformities in adult and pediatric patients (children and adolescents).

CONTRAINDICATIONS

Patients with any of the clinical conditions described below should not undergo procedures in which Pectus Versa System implants are used:

- Active infection or history of recent infection of local bone or soft tissue;
- Patients with insufficient bone tissue to allow correction;
- Patients with previously placed implants that could compromise implantation and/or interfere with the product;
- Mental illness;
- Drug abuse and alcoholism;
- Fever;
- Pregnancy;
- Lactating women;
- Allergy and/or sensitivity to metals.
- Patients who are unable to follow the recommendations of their doctor or healthcare team at any time during their treatment.

PURPOSE OR INTENDED USE OF THE PRODUCT

The Pectus Versa System consists of implants for treating chest wall deformities in adult and pediatric patients (children and adolescents). When implanted, the bars exert an internal force on the chest wall, enabling the repositioning of the bone structure of the thorax. The system has connecting bars and stabilizers that assist in the assembly of complex systems, stabilizing the system and connecting two or more bars, enabling the surgeon to apply minimally invasive techniques for treating chest wall deformities. The system are manufactured from titanium alloy, the plates range in thickness from 2.0 to 5.5.

The Pectus Versa System are for single use and the devices are provided non-sterile, and must be properly cleaned and sterilized before use, according to the recommendations provided in the Instructions for Use.

HOW SUPPLIED, PACKAGE AND PRODUCT TRACEABILITY PROCEDURE

Implantable components are supplied non-sterile and duly identified, that is, laser-marked with their code, batch number and GMReis logo. Their commercial presentation is individual plastic packaging, duly labeled on the back, where the components are supplied separately, image 1. The product is accompanied by traceability labels and a manual, showing how the user can obtain the product's Instructions for Use, in a non-printed format.

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677
 Techno Park, Campinas, SP, Brazil, Zip Code 13069320
 Phone: +551937659900, Email: gmreis@gmreis.com.br
 Website: www.gmreis.com.br

	Premarket Notification 510(k) - FDA	FORM. 02.1 - V	
		Issuance:	19/12/2023
		Revision:	00
		Sheet:	2/13



Image 1: Illustrative image of plastic packaging.

The Identification and traceability of the product are ensured through a set of 05 adhesive tags contained in the package, such as: name, model, code, lot, product registration and manufacturer identification. In this way it is possible to make the reverse path and reach a production, raw material, suppliers and other quality controls established in the GMReis Quality System. Traceability tags shall be fixed to the following locations:

- The tag number 1, obligatorily, in the patient's medical record;
- The tag number 2, in the report delivered to the patient;
- The tag number 3, in the tax documentation that generates the collection to the paying source;
- The tag number 4, available for supplier control (registration distribution history);
- The tag number 5, provided for the control of the doctor.

It is the responsibility of the medical and hospital staff (the custodians of patient information and records), the tag fixation on the surgical description sheet or a section of the medical chart. GMReis recommends that the patient receive this information, receiving a certificate stating one of the traceability adhesive tags.

HANDLING, CONSERVATION, STORAGE AND TRANSPORT

The hospital is responsible for the handling, conservation and storage of the products from the moment they are received and must ensure that the manufacturer's recommendations are followed, and that the product maintains its original characteristics.

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

The product must be preserved and stored in its original packaging until the moment of use, with due care from the medical-hospital area, in a clean, dry, ventilated environment, protected from sunlight and free from contaminating substances (acid and organic vapors), and with controls recommended, at room temperature. The product must be handled exclusively by professionals from the medical-hospital area, duly trained, qualified and familiar with the technique and procedures involved.

The effects of vibration, shocks, faulty seating and inadequate stacking during transportation must be avoided. Storage outside these conditions can generate risks to the procedure and to the patient.

SURGICAL TECHNIQUE

- a) Perform surgical planning by identifying the deformation reference points;
- b) Mark the locations of the lateral incisions for the implant to enter and exit the intercostal space;
- c) Position the Template (371-100/371-101) over the location where the bar will be placed;
- d) Check the size of the Pectus Bar to be used; the bar must cross the rib and be positioned laterally in the intercostal spaces, not exerting lateral pressure on the chest wall;
- e) Model the Template to the desired contour of the chest;
- f) Using the modeler (371-120), gradually transfer the modeling of the Template to the Pectus Bar; do not model at the ends of the Pectus Bar to ensure the assembly of the system;
- g) Make the entry and exit incisions of the Pectus Bar;
- h) Elevate the sternum;
- i) Dissect the canal through which the Pectus Bar will pass;

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677
 Techno Park, Campinas, SP, Brazil, Zip Code 13069320
 Phone: +551937659900, Email: gmreis@gmreis.com.br
 Website: www.gmreis.com.br

	Premarket Notification 510(k) - FDA	FORM. 02.1 - V	
		Issuance:	19/12/2023
		Revision:	00
		Sheet:	3/13

j) Insert the introducer (371-14X) laterally into the sternum through the canal, rotate and pass through the sternum until it exits through the opposite incision;

k) Attach a surgical tube or cardiac tape to the end of the introducer and remove the introducer, the surgical tube or cardiac tape should remain in the tunnel;

l) Attach the opposite end of the Pectus Bar to the surgical tube or cardiac tape;

m) Pass the Pectus Bar and the surgical tube or cardiac tape through the patient, the bar should be in the convex position facing posteriorly;

n) Remove the surgical tube or cardiac tape;

o) Place the positioners (371-150) on each end of the Pectus Bar, rotate the Pectus Bar 180° leaving the convex part facing anteriorly, remove the positioners and adjust the position of the Pectus Bar if necessary;

p) Repeat the previous steps to place the other Pectus Bars, it is recommended to use at least 02 (two) bars;

q) If the option is to use only 01 (one) bar, 02 (two) stabilizers (351-5X-XX) must be used, one at each end of the Pectus Bar;

r) If necessary, use the IN SITU modelers to model the Bar after insertion;

s) After implanting the Pectus Bars, connect the bars using the Connector Bar (371-05-XXX) in the size necessary for fixing between the bars and the locking screws (371-25), at least 02 (two) Connector Bars must be installed, one at each end of the system.

t) At the end of the procedure, make sure to evacuate the residual air and close the incisions.

Post-operative care and rehabilitation will depend on numerous variables that cannot be outlined in this document and that are the sole responsibility of the multidisciplinary team caring for the patient.

The patient must be handled with care in the post-operative period to avoid displacement of the system.

This system is used to treat chest wall deformities and must be removed after correction and healing. The time required and the method of removal must be determined by the surgeon in charge.

INDICATION OF TRAINING

Only surgeons qualified and trained in thoracic surgery procedures should handle this product.

The surgeon must be familiar with the implants and procedure, aware of all recommendations described in the product's "instructions for use" and other information described on the label.

The Pectus Versa System was developed for the treatment of congenital deformities of the chest wall that in many cases affect respiratory and cardiac functions. This system does not have the function of replacing bone structure. The main function is to expand the chest cavity to correct the deformation, but it is not possible to determine the success of the correction because it depends on each case.

CAUTION/PRECAUTIONS

The Pectus Versa System is indicated for the treatment of Pectus Excavatum and other chest wall deformities in adult and pediatric patients (children and adolescents). Overloads exerted during the handling and implantation of the product compromise the mechanical characteristics, which may lead to failure during the surgical procedure.

The Pectus Bar must be shaped to achieve the desired contour of the chest. It should not be shaped in a single step. Sharp folds should be avoided. It should not be shaped in areas with holes. Once shaped, it cannot be returned to the flat position.

Undesirable side effects or collateral effects

- Allergic reaction or sensitivity to the implant material;
- Pain, discomfort, or abnormal sensation caused by the presence of the device;
- Surgical trauma, temporary or permanent damage to the heart, lungs, body structures, nerves, tissues or other organs;
- Pneumonia, pneumothorax, hemothorax;
- Pleural effusion;

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677
 Techno Park, Campinas, SP, Brazil, Zip Code 13069320
 Phone: +551937659900, Email: gmreis@gmreis.com.br
 Website: www.gmreis.com.br

	Premarket Notification 510(k) - FDA	FORM. 02.1 - V	
		Issuance:	19/12/2023
		Revision:	00
		Sheet:	4/13

- Skin irritations, incision or wound infection;
- Seroma, hematoma, post-operative bleeding;
- Fracture of the sternum;
- Fracture, breakage, migration, rotation or loosening of the system;
- Inadequate or incomplete correction of the deformity, or failure of correction, before or after removal of the implant;
- Dressler's syndrome, thoracic outlet syndrome.

CRITERIA FOR SIZE SELECTION

It is the responsibility of the surgeon responsible for the procedure to select the most appropriate size of the implantable component for use, which should be done based on the preoperative radiological study and the correct indication for use.

Preoperative planning is necessary for the correct selection of the implant, which is related to the success of the treatment, and must consider the biomechanical aspects, the size and shape of the bone structure to be treated, which corresponds to the size and model of the selected implant and the final position of the implant.

PATIENT INSTRUCTIONS

The patient must be warned by the surgeon in charge about the limits of his/her initial activities and about his/her rehabilitation in order to protect the surgery performed.

It is the responsibility of the surgeon in charge to make post-operative recommendations, follow-ups and clinical progress of the patient.

The patient must be informed that although the raw material used to manufacture the Pectus Versa System is recognized as biocompatible, other side effects or adverse reactions may occur in more sensitive patients.

WARNING REGARDING THE PRODUCT CONDITION WHICH RESTRICT THE USE

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 send the product for cleaning, disinfection and sterilization, following the indicated recommendations.

CAUTION ASSOCIATED IN CASE OF FALL OF SOME COMPONENT

In case of the fall of any component or suffering any kind of damage, it should be destroyed and disposed of according to the Procedure of Disposal.

FACTORS THAT MAY CAUSE THE IMPLANT TO A POSSIBLE BREACH, LOOSENING, DISPLACEMENT OR HEATING WHICH SHOULD BE INFORMED THE PATIENT

The following are the main factors that, alone or in combination, can lead to early implant failure (breakage, loosening or migration) and alter the speed of tissue recovery (healing):

- Failure to follow post-operative recommendations and instructions for use;
- Metabolic dysfunctions;
- Diabetes;
- Smoking;
- Patients who have used or are using anabolic steroids;
- Inadequate choice of implants.

PROCEDURE FOR DISPOSAL TO ENSURE THE DESTRUCTION OF THE PRODUCT

The implants which for some reason were not used during the surgery and had the package open or suffered damage and/or falls may not be re-used and/or re-sterilized and should be discarded in the hospital as the medical procedure hospital and/or local law or as instructed by the Commission of Hospital Infection Control - CHIC. The methods and procedures for product disposing should ensure the complete mischaracterization

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677
 Techno Park, Campinas, SP, Brazil, Zip Code 13069320
 Phone: +551937659900, Email: gmreis@gmreis.com.br
 Website: www.gmreis.com.br

	Premarket Notification 510(k) - FDA	FORM. 02.1 - V	
		Issuance:	19/12/2023
		Revision:	00
		Sheet:	5/13

of it, preventing any possibility of reuse. The adulteration of the product is the sole responsibility of the hospital institution, as well as the methods and procedures for disposing used.

It is recommended that they be deformed with molders or twistors until they are clearly identified that the product is inappropriate for your use, ensuring that the product may not be used or improperly reused.

REMOVING AND HANDLING OF IMPLANTS REMOVED FROM PATIENTS FOR ANALYSIS

When the implant is removed from the patient and/or needs to be submitted for analysis, the procedure must be followed in accordance with ABNT NBR ISO 12891-1.

The instructions below should be followed for the correct handling of these products:

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

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

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

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

Removing implants must undergo a cleaning and disinfection process. They must then be packaged separately in plastic bags or plastic/glass containers and labeled. The packaging must minimize the possibility of breakage, surface damage and possible contamination of the implant by the environment. The labeling of products to be sent for analysis must ensure their accurate identification, and the ABNT NBR ISO 12891-1 standard recommends the use of non-removable labels (which tear if attempted removal).

For an accurate assessment of the cause of product failure, it is extremely important that pre- and post-operative X-rays and X-rays of the implant failure verification be sent together with the material sent for analysis.

ADMISSIBLE COMBINATIONS WITH OTHER MATERIALS

Titanium Alloy materials are highly resistant to corrosion in the physiological environment. Despite this, the product cannot be used in conjunction with any product from another manufacturer, or any metal product with a different chemical composition, as these combinations can generate chemical incompatibilities (producing galvanic corrosion and others), physical, biological and functional incompatibilities, early fatigue and possible risks to the patient.

The product should only be implanted with specific GMReis brand instruments, indicated for this purpose.

If any improper combination occurs by the surgeon, he will be responsible for the risks associated with such combination.

USEFUL INFORMATION TO PREVENT RISKS ARISING OUT OF THE IMPLANTATION

To reduce the risks of implanting the product, the recommendations regarding indications for use, contraindications and the information described in the "Instructions for Use" must be followed.

Detailed instructions regarding the use and limitations of the product must be given to the patient.

Preoperative and operating room procedures, including knowledge of surgical techniques, appropriate selection of implant size, and proper implantation of the implant, are important considerations for the successful use of this device.

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677

Techno Park, Campinas, SP, Brazil, Zip Code 13069320

Phone: +551937659900, Email: gmreis@gmreis.com.br

Website: www.gmreis.com.br

	Premarket Notification 510(k) - FDA	FORM. 02.1 - V	
		Issuance:	19/12/2023
		Revision:	00
		Sheet:	6/13

Assessment of the product deployed

It is up to the surgeon in charge to carry out post-operative assessments and monitor the patient's healing process.

Restrictions and instructions on the damage of the packaging

In the circumstances described below, the product must be unusable and discarded, as the procedure of destruction and disposal:

- The sealing area of the package is violated.
- Any one of the packages present physical damage;
- The label or identification code is unreadable.

Restrictions on reusing

The reuse and reprocessing of the product 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, and may put the health of patients and healthcare professionals at risk.

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 standards, 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.

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

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677
 Techno Park, Campinas, SP, Brazil, Zip Code 13069320
 Phone: +551937659900, Email: gmreis@gmreis.com.br
 Website: www.gmreis.com.br

	Premarket Notification 510(k) - FDA	FORM. 02.1 - V	
		Issuance:	19/12/2023
		Revision:	00
		Sheet:	7/13

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

Manual Cleaning

- In a sink the devices must be 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 heated 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 heated 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 soil or contaminants.
- Then, immerse the devices 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 solutions previously 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.

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677
 Techno Park, Campinas, SP, Brazil, Zip Code 13069320
 Phone: +551937659900, Email: gmreis@gmreis.com.br
 Website: www.gmreis.com.br

	Premarket Notification 510(k) - FDA	FORM. 02.1 - V	
		Issuance:	19/12/2023
		Revision:	00
		Sheet:	8/13

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.

STERILIZATION

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 the sole responsibility of the health service. GMReis recommends the following validated cycle:

STEAM STERILIZATION CYCLE

Type: moist heat

Cycle: gravity-displacement

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".

NOTE: Orthopaedic surgical devices generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Devices which no longer perform properly because of long use, mishandling, or improper care should be returned to GMReis to be discarded. Notify your GMReis representative of any instrument problems.

MRI Safety Information

The Pectus Versa System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifacts in the MR environment. The safety of Pectus Versa System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Specific guidance to the physician regarding the reporting of adverse events

If the product presents adverse events not reported in the instructions for use or there are technical complaints about the product, the physician should immediately contact the manufacturer through GMReis Customer Service (SAC), in addition to notifying the competent sanitary authority. To ensure the traceability of the product, the physician should continue as the "Procedure for product traceability". The traceability of the product is ensured by the 05 labels of traceability provided within the packaging, along with the instructions for use, as described in the topic "Product Traceability Procedure".

Customer Complaint

If the medical product presents a risk specific unpredictable, being outside of its specifications or being generated any dissatisfaction, notify directly the GMReis Customer Service (SAC). The product should be sent cleaned and packed in plastic bag, properly identified and with the description of non-compliance to the following address:

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677

Techno Park, Campinas, SP, Brazil, Zip Code 13069320

Phone: +551937659900, Email: gmreis@gmreis.com.br

Website: www.gmreis.com.br

	Premarket Notification 510(k) - FDA	FORM. 02.1 - V	
		Issuance:	19/12/2023
		Revision:	00
		Sheet:	9/13

G. M. dos Reis Indústria e Comércio Ltda - Pierre Simon de Laplace Avenue, no. 600 Lote 3 - Quadra F – Quarteirão 9677 - TECHNOPARK – CEP: 13069-320 – Campinas – SP – BRAZIL or directly notify at Telephone Number:(0xx19)3765-9900/ E-mail: sac@gmreis.com.br.

Symbolism of labeling

The graphic symbols used in labeling are in accordance with the ISO 15223 Standard.

Table 1 - Description of the information on the packaging label

Symbol	Description	Symbol	Description
	Manufacturing date	LOT	Lot number
	Manufactured by		Caution "see instructions for use"
	Expiration date		Keep away from sunlight
	Keep dry		Do not use it if package is damaged
Rx only	Prescription use only		Do not re-sterilize
	Non-Sterile	COD	Product catalogue number
	Do not reuse	QT	Quantity

User Warning

These Instructions for Use are available in format that is not printed, through the electronic address of the manufacturer: <http://www.gmreis.com.br/produtos/IFU>. 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 physician.

Company Name / Manufacturer Name:

GM dos Reis Indústria e Comércio Ltda.
Avenida Pierre Simon de Laplace, no. 600 Lote 3 - Quadra F - Quarteirão 9677
TECHNOPARK – CEP: 13069-320 – Campinas – SP - BRAZIL
C.N.P.J/Tax ID: 60.040.599/0001-19
Email: qualidade@gmreis.com.br
Telephone number: +55 (0XX19) 3765-9900

PECTUS EN, Revision 00, April 01, 2025.

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677
Techno Park, Campinas, SP, Brazil, Zip Code 13069320
Phone: +551937659900, Email: gmreis@gmreis.com.br
Website: www.gmreis.com.br



Premarket Notification 510(k) - FDA

FORM. 02.1 - V

Issuance:	19/12/2023
Revision:	00
Sheet:	10/13

Table 2 - Product codes

CODE	DESCRIPTION	IMAGE
371-01-180	PECTUS BAR - STRAIGHT 180.0mm	
371-01-190	PECTUS BAR - STRAIGHT 190.0mm	
371-01-200	PECTUS BAR - STRAIGHT 200.0mm	
371-01-210	PECTUS BAR - STRAIGHT 210.0mm	
371-01-220	PECTUS BAR - STRAIGHT 220.0mm	
371-01-230	PECTUS BAR - STRAIGHT 230.0mm	
371-01-240	PECTUS BAR - STRAIGHT 240.0mm	
371-01-250	PECTUS BAR - STRAIGHT 250.0mm	
371-01-260	PECTUS BAR - STRAIGHT 260.0mm	
371-01-270	PECTUS BAR - STRAIGHT 270.0mm	
371-01-280	PECTUS BAR - STRAIGHT 280.0mm	
371-01-290	PECTUS BAR - STRAIGHT 290.0mm	
371-01-300	PECTUS BAR - STRAIGHT 300.0mm	
371-01-310	PECTUS BAR - STRAIGHT 310.0mm	
371-01-320	PECTUS BAR - STRAIGHT 320.0mm	
371-01-330	PECTUS BAR - STRAIGHT 330.0mm	
371-01-340	PECTUS BAR - STRAIGHT 340.0mm	
371-01-350	PECTUS BAR - STRAIGHT 350.0mm	
371-01-360	PECTUS BAR - STRAIGHT 360.0mm	
371-01-370	PECTUS BAR - STRAIGHT 370.0mm	
371-01-380	PECTUS BAR - STRAIGHT 380.0mm	
371-01-390	PECTUS BAR - STRAIGHT 390.0mm	
371-01-400	PECTUS BAR - STRAIGHT 400.0mm	
371-01-410	PECTUS BAR - STRAIGHT 410.0mm	
371-01-420	PECTUS BAR - STRAIGHT 420.0mm	
371-02-180	PECTUS BAR - ANGLED 180.0mm	
371-02-190	PECTUS BAR - ANGLED 190.0mm	
371-02-200	PECTUS BAR - ANGLED 200.0mm	
371-02-210	PECTUS BAR - ANGLED 210.0mm	
371-02-220	PECTUS BAR - ANGLED 220.0mm	
371-02-230	PECTUS BAR - ANGLED 230.0mm	
371-02-240	PECTUS BAR - ANGLED 240.0mm	
371-02-250	PECTUS BAR - ANGLED 250.0mm	

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677

Techno Park, Campinas, SP, Brazil, Zip Code 13069320

Phone: +551937659900, Email: gmreis@gmreis.com.br

Website: www.gmreis.com.br



Premarket Notification 510(k) - FDA

FORM. 02.1 - V

Issuance:	19/12/2023
Revision:	00
Sheet:	11/13

371-02-260	PECTUS BAR - ANGLED 260.0mm	
371-02-270	PECTUS BAR - ANGLED 270.0mm	
371-02-280	PECTUS BAR - ANGLED 280.0mm	
371-02-290	PECTUS BAR - ANGLED 290.0mm	
371-02-300	PECTUS BAR - ANGLED 300.0mm	
371-02-310	PECTUS BAR - ANGLED 310.0mm	
371-02-320	PECTUS BAR - ANGLED 320.0mm	
371-02-330	PECTUS BAR - ANGLED 330.0mm	
371-02-340	PECTUS BAR - ANGLED 340.0mm	
371-02-350	PECTUS BAR - ANGLED 350.0mm	
371-02-360	PECTUS BAR - ANGLED 360.0mm	
371-02-370	PECTUS BAR - ANGLED 370.0mm	
371-02-380	PECTUS BAR - ANGLED 380.0mm	
371-02-390	PECTUS BAR - ANGLED 390.0mm	
371-02-400	PECTUS BAR - ANGLED 400.0mm	
371-02-410	PECTUS BAR - ANGLED 410.0mm	
371-02-420	PECTUS BAR - ANGLED 420.0mm	
371-03-180	EXTERNAL PECTUS BAR - STRAIGHT 180.0mm	
371-03-190	EXTERNAL PECTUS BAR - STRAIGHT 190.0mm	
371-03-200	EXTERNAL PECTUS BAR - STRAIGHT 200.0mm	
371-03-210	EXTERNAL PECTUS BAR - STRAIGHT 210.0mm	
371-03-220	EXTERNAL PECTUS BAR - STRAIGHT 220.0mm	
371-03-230	EXTERNAL PECTUS BAR - STRAIGHT 230.0mm	
371-03-240	EXTERNAL PECTUS BAR - STRAIGHT 240.0mm	
371-03-250	EXTERNAL PECTUS BAR - STRAIGHT 250.0mm	
371-03-260	EXTERNAL PECTUS BAR - STRAIGHT 260.0mm	
371-03-270	EXTERNAL PECTUS BAR - STRAIGHT 270.0mm	
371-03-280	EXTERNAL PECTUS BAR - STRAIGHT 280.0mm	
371-03-290	EXTERNAL PECTUS BAR - STRAIGHT 290.0mm	
371-03-300	EXTERNAL PECTUS BAR - STRAIGHT 300.0mm	
371-03-310	EXTERNAL PECTUS BAR - STRAIGHT 310.0mm	
371-03-320	EXTERNAL PECTUS BAR - STRAIGHT 320.0mm	
371-03-330	EXTERNAL PECTUS BAR - STRAIGHT 330.0mm	
371-03-340	EXTERNAL PECTUS BAR - STRAIGHT 340.0mm	
371-03-350	EXTERNAL PECTUS BAR - STRAIGHT 350.0mm	

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677

Techno Park, Campinas, SP, Brazil, Zip Code 13069320

Phone: +551937659900, Email: gmreis@gmreis.com.br

Website: www.gmreis.com.br



Premarket Notification 510(k) - FDA

FORM. 02.1 - V

Issuance: 19/12/2023

Revision: 00

Sheet: 12/13

371-03-360	EXTERNAL PECTUS BAR - STRAIGHT 360.0mm	
371-03-370	EXTERNAL PECTUS BAR - STRAIGHT 370.0mm	
371-03-380	EXTERNAL PECTUS BAR - STRAIGHT 380.0mm	
371-03-390	EXTERNAL PECTUS BAR - STRAIGHT 390.0mm	
371-03-400	EXTERNAL PECTUS BAR - STRAIGHT 400.0mm	
371-03-410	EXTERNAL PECTUS BAR - STRAIGHT 410.0mm	
371-03-420	EXTERNAL PECTUS BAR - STRAIGHT 420.0mm	
371-05-30	CONECTOR BAR - 30.0mm	
371-05-40	CONECTOR BAR - 40.0mm	
371-05-50	CONECTOR BAR - 50.0mm	
371-05-60	CONECTOR BAR - 60.0mm	
371-05-70	CONECTOR BAR - 70.0mm	
371-05-80	CONECTOR BAR - 80.0mm	
371-05-90	CONECTOR BAR - 90.0mm	
371-05-100	CONECTOR BAR - 100.0mm	
371-05-110	CONECTOR BAR - 110.0mm	
371-05-120	CONECTOR BAR - 120.0mm	
371-05-130	CONECTOR BAR - 130.0mm	
371-05-140	CONECTOR BAR - 140.0mm	
371-05-150	CONECTOR BAR - 150.0mm	
371-50-60	NEUTRAL STABILIZER	
371-50-70	NEUTRAL OFFSET STABILIZER	
371-50-80	NEUTRAL LONG STABILIZER	
371-51-60	ANGLED STABILIZER 10°-R	
371-52-60	ANGLED STABILIZER 20°-R	
371-51-70	ANGLED OFFSET STABILIZER 10°-R	
371-52-70	ANGLED OFFSET STABILIZER 20°-R	

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677

Techno Park, Campinas, SP, Brazil, Zip Code 13069320

Phone: +551937659900, Email: gmreis@gmreis.com.br

Website: www.gmreis.com.br



Premarket Notification 510(k) - FDA

FORM. 02.1 - V

Issuance: 19/12/2023

Revision: 00

Sheet: 13/13

371-51-80	ANGLED LONG STABILIZER 10°-R	
371-52-80	ANGLED LONG STABILIZER 20°-R	
371-53-60	ANGLED STABILIZER 10°-L	
371-54-60	ANGLED STABILIZER 20°-L	
371-53-70	ANGLED OFFSET STABILIZER 10°-L	
371-54-70	ANGLED OFFSET STABILIZER 20°-L	
371-53-80	ANGLED LONG STABILIZER 10°-L	
371-54-80	ANGLED LONG STABILIZER 20°-L	
371-25	LOCKING SCREW	
371-26	EXTERNAL LOCKING SCREW	

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., 600, Block 3F9677
 Techno Park, Campinas, SP, Brazil, Zip Code 13069320
 Phone: +551937659900, Email: gmreis@gmreis.com.br
 Website: www.gmreis.com.br