

Section 21_Appendix 1 - Instructions for Use

INSTRUCTIONS FOR USE

Quick - Radius Disposable Set

DEVICE DESCRIPTION

Quick - Radius Disposable Set are plate and instruments kit, for osteosynthesis procedures of the distal radius, in sterile condition, single use and disposable instruments after use. This sterile set must be used with 2.4mm screws, also sterile and individually packaged. The surgeon selects the best combination of plate size, left or right and screw designs and quantities, as needed. Single use and sterile templates are available, individually packed, for determining the size of the plate to be used. Also, as an option, individually packed plates, instruments only kit, and instruments with plates and screws kit, are available in sterile condition.

The plates and screws are produced with Titanium Alloy, according with standard ASTM F136, and the instruments are made of Stainless Steel, according with standard ASTM F899.

HOW SUPPLIED

The product is supplied sterile, properly identified, i.e., laser marking with the following information: batch of production, product code, and GMReis logo brand.

Identification and traceability of the product are ensured through a set of 05 adhesive tags contained into the package, along with the instructions for use.

INDICATIONS FOR USE

Quick - Radius Disposable Set is intended for fracture fixation, arthrodesis, reconstruction, and osteotomy fixation of the hand and wrist. The use of locking plate and screw systems is suited for treatment of fractures in osteopenic bone.

CONTRAINDICATIONS

Contraindications include those listed below, but are not limited to:

- Active infection or history of recent infection of bone tissue or of soft parts locations;
- Osteometabolic diseases that cause weakness or reduction of bone mass;
- Insufficient bone mass or poor bone quality;
- Inadequate vascularization in the implant site location that could compromise the adequate blood supply;
- Patients with previously implants that may impact and/or interfere with the product;
- Drugs abuse and alcoholism.
- Fever;
- Allergy and/or sensitivity to metals.
- Patients without conditions to follow the medical advice and the health team at any time of their treatment.

WARNINGS AND PRECAUTIONS

- These implants are designed to support distributed loads on their surface when implanted for stabilization of a particular bone structure and may rupture until total bone healing occurs.
- It is not recommended plate modification or modeling. Modifying plate curvature and shape can affect its mechanical characteristics, causing fatigue fail or loss of function.
- Implants allow for early patient mobility, under limited to no-load movements and efforts. Surgeon, using follow-up protocols, can evaluate bone fracture consolidation and load and/or movements post-surgery.
- The implants are designed as a support to the natural consolidation process but are not intended to replace anatomical structures or support body weight and loads before bone healing.

- Until full load is permitted, patient should follow all the surgeon's recommendations.

Main factors leading to premature failure, alone or in combination:

- Disregard with the postoperative recommendations;
- Metabolic disorders;
- Diabetes
- Smoking
- Patient accident (e.g., falls, accidents);
- Pseudo arthrosis;
- Delay in bone consolidation;
- Failure following recommended surgical technique;
- Inappropriate choice of implant;
- Early releasing of load;
- Lack of use of external support, when recommended;
- Excessive load or inappropriate activity;
- Drugs that can lead to a delay of the bone consolidation and pseudo arthrosis;
- Osteoporosis;
- Practice of intense physical activity;
- Practice of physical activity without medical approval;

MRI SAFETY INFORMATION

The Quick - Radius Disposable Set has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety Quick - Radius Disposable Set in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POTENTIAL ADVERSE EVENTS

- Allergic reactions to any metal component;
- Bone deformity under premature load or movement;
- Incomplete bone consolidation.

STORAGE

The product must be preserved, handled, and transported in order to prevent any damage or modification to its characteristics and packaging. Refer to package symbols.

It must be preserved and stored in its original packaging until the moment of use, with the proper care of the medical and hospital area, in a clean, dry, ventilated environment protected from sunlight and free of contaminants.

INSTRUCTION FOR THE CORRECT USE

- 1- Perform the pre-operative clinical planning; using images and size selection
- 2- Positioning the patient and performing the incision and access;
- 3- Select the most appropriate implant Kit;
- 4- Reduce the fracture and place the plate; keep it positioned;
- 5- Position the plate and fix it;
- 6- Perform the fixation of the plate on the bone tissue with screws chosen by the technique selected by the surgeon in charge;
- 7- Perform the radiological evaluation to check the positioning of the plate and the screws;
- 8- Close access.

Implant Removal:

The single-use T7 screwdriver is designed to facilitate implant removal without the need for a new complete sterile instrument kit. Before attempting screw removal clean all screw head recesses of tissue or ingrown/overgrown bone using an appropriate instrument.

To remove locking screws, first unlock all screws from the plate; then remove the screws completely from the bone.

The last screw removed should be a non-locking screw on the shaft. This prevents the plate from spinning when locking screws are removed.

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

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

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		Do not resterilize
	Sterile by Ethylene Oxide		Product catalogue number
	Do not reuse		

COMPANY NAME / MANUFACTURER NAME:

GM dos Reis Industria e Comercio Ltda.

Pierre Simon de Laplace Ave., no. 600 Lot 3, Block F 9677, Techno Park

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Revision: 0, January 11, 2024

Code	Description	Dimensions (mm)	Thickness (mm)	Image
180-52-S	Volar FLP Versalock Plate Small Left	50x25	2.0	
180-53-S	Volar FLP Versalock Plate Small Right	50x25	2.0	
180-54-S	Volar FLP Versalock Plate Large Left	62x25	2.0	
180-55-S	Volar FLP Versalock Plate Large Right	62x25	2.0	

Code	Components	Qt.	Description	Image
358-180-CX-TPL	358-180-52-TPL	1	FLP Small Template Left/Right - Single Use	
	358-180-54-TPL	1	FLP Large Template Left/Right - Single Use	

Code	Description	Dimensions (mm)	Image
223-24-08-CS	Mini Versa Screw Ti T7 Ø2.4x08.0mm	Ø2.4x08.0	
223-24-10-CS	Mini Versa Screw Ti T7 Ø2.4x10.0mm	Ø2.4x10.0	
223-24-12-CS	Mini Versa Screw Ti T7 Ø2.4x12.0mm	Ø2.4x12.0	
223-24-14-CS	Mini Versa Screw Ti T7 Ø2.4x14.0mm	Ø2.4x14.0	
223-24-16-CS	Mini Versa Screw Ti T7 Ø2.4x16.0mm	Ø2.4x16.0	
223-24-18-CS	Mini Versa Screw Ti T7 Ø2.4x18.0mm	Ø2.4x18.0	

Code	Description	Dimensions (mm)	Image
223-24-08-BPS	Versalock Screw Ti T7 Ø2.4x08.0mm	Ø2.4x08.0	
223-24-10-BPS	Versalock Screw Ti T7 Ø2.4x10.0mm	Ø2.4x10.0	
223-24-12-BPS	Versalock Screw Ti T7 Ø2.4x12.0mm	Ø2.4x12.0	
223-24-14-BPS	Versalock Screw Ti T7 Ø2.4x14.0mm	Ø2.4x14.0	
223-24-16-BPS	Versalock Screw Ti T7 Ø2.4x16.0mm	Ø2.4x16.0	
223-24-18-BPS	Versalock Screw Ti T7 Ø2.4x18.0mm	Ø2.4x18.0	
223-24-20-BPS	Versalock Screw Ti T7 Ø2.4x20.0mm	Ø2.4x20.0	
223-24-22-BPS	Versalock Screw Ti T7 Ø2.4x22.0mm	Ø2.4x22.0	
223-24-24-BPS	Versalock Screw Ti T7 Ø2.4x24.0mm	Ø2.4x24.0	
223-24-26-BPS	Versalock Screw Ti T7 Ø2.4x26.0mm	Ø2.4x26.0	
223-24-28-BPS	Versalock Screw Ti T7 Ø2.4x28.0mm	Ø2.4x28.0	
223-24-30-BPS	Versalock Screw Ti T7 Ø2.4x30.0mm	Ø2.4x30.0	

MATRIZ | HEADQUARTER

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Kit Code	Components Code	Qt.	Description	Image
358-1000	358-T7-140	1	Torque Limiter 0.8Nm AO Coupling	
	358-T7-17-AO	1	Drill Ø1.8x123mm AO Coupling	
	358-T7-130	1	T7 Hexalobular Shaft	
	358-T7-16G	1	Straight and Variable Drill Guide with Depth Gauge	
	358-T7-120	3	Guide Wire Ø1.0x120.0mm	
	358-180-52	1	Volar FLP Versalock Plate Small Left	
Quick - Radius Disposable Set - Small Plate Left				
358-2000	358-T7-140	1	Torque Limiter 0.8Nm AO Coupling	
	358-T7-17-AO	1	Drill Ø1.8x123mm AO Coupling	
	358-T7-130	1	T7 Hexalobular Shaft	
	358-T7-16G	1	Straight and Variable Drill Guide with Depth Gauge	
	358-T7-120	3	Guide Wire Ø1.0x120.0mm	
	358-180-53	1	Volar FLP Versalock Plate Small Right	
Quick - Radius Disposable Set - Small Plate Right				

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358-3000	358-T7-140	1	Torque Limiter 0.8Nm AO Coupling	
	358-T7-17-AO	1	Drill Ø1.8x123mm AO Coupling	
	358-T7-130	1	T7 Hexalobular Shaft	
	358-T7-16G	1	Straight and Variable Drill Guide with Depth Gauge	
	358-T7-120	3	Guide Wire Ø1.0x120.0mm	
	358-180-54	1	Volar FLP Versalock Plate Large Left	
Quick - Radius Disposable Set - Large Plate Left				
358-4000	358-T7-140	1	Torque Limiter 0.8Nm AO Coupling	
	358-T7-17-AO	1	Drill Ø1.8x123mm AO Coupling	
	358-T7-130	1	T7 Hexalobular Shaft	
	358-T7-16G	1	Straight and Variable Drill Guide with Depth Gauge	
	358-T7-120	3	Guide Wire Ø1.0x120.0mm	
	358-180-55	1	Volar FLP Versalock Plate Large Right	
Quick - Radius Disposable Set - Large Plate Right				

358-1001	358-T7-140	1	Torque Limiter 0.8Nm AO Coupling
	358-T7-17-AO	1	Drill Ø1.8x123mm AO Coupling
	358-T7-130	1	T7 Hexalobular Shaft
	358-T7-16G	1	Straight and Variable Drill Guide with Depth Gauge
	358-T7-120	3	Guide Wire Ø1.0x120.0mm
	358-180-52	1	Volar FLP Versalock Plate Small Left
	358-223-24-12-C	1	Mini Versa Screw Ti T7 Ø2.4x12.0mm
	358-223-24-14-C	1	Mini Versa Screw Ti T7 Ø2.4x14.0mm
	358-223-24-12-BP	2	Versalock Screw Ti T7 Ø2.4x12.0mm
	358-223-24-14-BP	3	Versalock Screw Ti T7 Ø2.4x14.0mm
	358-223-24-16-BP	3	Versalock Screw Ti T7 Ø2.4x16.0mm
	358-223-24-18-BP	2	Versalock Screw Ti T7 Ø2.4x18.0mm
	358-223-24-20-BP	2	Versalock Screw Ti T7 Ø2.4x20.0mm
	358-223-24-22-BP	1	Versalock Screw Ti T7 Ø2.4x22.0mm



Quick - Radius Disposable Set - Small Plate Left and Screws

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358-2001	358-T7-140	1	Torque Limiter 0.8Nm AO Coupling
	358-T7-17-AO	1	Drill Ø1.8x123mm AO Coupling
	358-T7-130	1	T7 Hexalobular Shaft
	358-T7-16G	1	Straight and Variable Drill Guide with Depth Gauge
	358-T7-120	3	Guide Wire Ø1.0x120.0mm
	358-180-53	1	Volar FLP Versalock Plate Small Right
	358-223-24-12-C	1	Mini Versa Screw Ti T7 Ø2.4x12.0mm
	358-223-24-14-C	1	Mini Versa Screw Ti T7 Ø2.4x14.0mm
	358-223-24-12-BP	2	Versalock Screw Ti T7 Ø2.4x12.0mm
	358-223-24-14-BP	3	Versalock Screw Ti T7 Ø2.4x14.0mm
	358-223-24-16-BP	3	Versalock Screw Ti T7 Ø2.4x16.0mm
	358-223-24-18-BP	2	Versalock Screw Ti T7 Ø2.4x18.0mm
	358-223-24-20-BP	2	Versalock Screw Ti T7 Ø2.4x20.0mm
	358-223-24-22-BP	1	Versalock Screw Ti T7 Ø2.4x22.0mm



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358-3001	358-T7-140	1	Torque Limiter 0.8Nm AO Coupling
	358-T7-17-AO	1	Drill Ø1.8x123mm AO Coupling
	358-T7-130	1	T7 Hexalobular Shaft
	358-T7-16G	1	Straight and Variable Drill Guide with Depth Gauge
	358-T7-120	3	Guide Wire Ø1.0x120.0mm
	358-180-54	1	Volar FLP Versalock Plate Large Left
	358-223-24-12-C	1	Mini Versa Screw Ti T7 Ø2.4x12.0mm
	358-223-24-14-C	1	Mini Versa Screw Ti T7 Ø2.4x14.0mm
	358-223-24-12-BP	3	Versalock Screw Ti T7 Ø2.4x12.0mm
	358-223-24-14-BP	4	Versalock Screw Ti T7 Ø2.4x14.0mm
	358-223-24-16-BP	3	Versalock Screw Ti T7 Ø2.4x16.0mm
	358-223-24-18-BP	2	Versalock Screw Ti T7 Ø2.4x18.0mm
	358-223-24-20-BP	2	Versalock Screw Ti T7 Ø2.4x20.0mm
	358-223-24-22-BP	1	Versalock Screw Ti T7 Ø2.4x22.0mm



Quick - Radius Disposable Set - Large Plate Left and Screws

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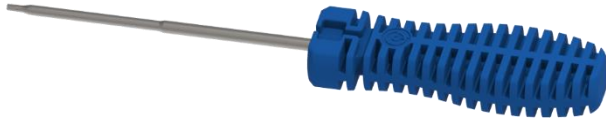
358-4001	358-T7-140	1	Torque Limiter 0.8Nm AO Coupling
	358-T7-17-AO	1	Drill Ø1.8x123mm AO Coupling
	358-T7-130	1	T7 Hexalobular Shaft
	358-T7-16G	1	Straight and Variable Drill Guide with Depth Gauge
	358-T7-120	3	Guide Wire Ø1.0x120.0mm
	358-180-55	1	Volar FLP Versalock Plate Large Right
	358-223-24-12-C	1	Mini Versa Screw Ti T7 Ø2.4x12.0mm
	358-223-24-14-C	1	Mini Versa Screw Ti T7 Ø2.4x14.0mm
	358-223-24-12-BP	3	Versalock Screw Ti T7 Ø2.4x12.0mm
	358-223-24-14-BP	4	Versalock Screw Ti T7 Ø2.4x14.0mm
	358-223-24-16-BP	3	Versalock Screw Ti T7 Ø2.4x16.0mm
	358-223-24-18-BP	2	Versalock Screw Ti T7 Ø2.4x18.0mm
	358-223-24-20-BP	2	Versalock Screw Ti T7 Ø2.4x20.0mm
	358-223-24-22-BP	1	Versalock Screw Ti T7 Ø2.4x22.0mm



Quick - Radius Disposable Set - Large Plate Right and Screws

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358-1010	358-T7-140	1	Torque Limiter 0.8Nm AO Coupling	
	358-T7-17-AO	1	Drill Ø1.8x123mm AO Coupling	
	358-T7-130	1	T7 Hexalobular Shaft	
	358-T7-16G	1	Straight and Variable Drill Guide with Depth Gauge	
	358-T7-120	3	Guide Wire Ø1.0x120.0mm	
Quick - Radius Disposable Set - Instruments				
358-1020				
Quick - Radius Disposable Set - Remove				

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