



### ATTENTION



The use of Riellen's Gloves and Copings are of specific use for qualified professionals, with specific training in prosthetics, implantology, including diagnosis, planning and protocol surgical. They are indicated for laboratory and surgical use. Gloves and Copings supplied by Riellen's are available in **Non-Sterile condition**. Never use products Riellen's without carrying out the sterilization process.

## 1 - Intentions of Use

Riellen's Gloves and Copings have the function of replacing or replacing the tooth structure in order to reestablish the patient's masticatory and aesthetic functions

## 2 - The indication of the Use

The indication for the use of the Glove and Coping is guided according to the following table:

RIELLEN'S GLOVE / COPING COMPONENTS							
COMPO NENTS	INDICATION FOR USE	TEMPLATES		FEATURES		CONNECTI ON	DIAMETER
	Used for waxing and casting single or multiple bolted prosthetic crown structures.	Base CrCo	The Cobalt Chromium base does not change its structure, offering greater precision in the adaptation of the prosthesis to the implant.	Anti Rotaci- onal	Used for single prosthet ic crowns	HE	NP, RP WP
				Rotaci- onal	Used for multiple single prosthe tic crowns		Ø 3.3, 3.75, 3.5/4.0, 4.5/5.0, NP, RP, WP
	Used for waxing and casting single or multiple bolted prosthetic crown structures.	Plastic surgery	Product undergoes degradat ion in the casting process	Anti Rotaci- onal	Used for single protetic crowns	TI	Ø 3.3, 4.0, NP, RP, WP
				Rotaci- onal	Used for multiple single protein crowns		Ø3.0, 3.8, 4.5, 4.5/5.0, NN, NP, RN, RP, WN, NC, RC

**Legend:** HE: Outer Hexagon; HI: Inner Hexagon; CM: Morse taper; TI: Inner Triangle

**Warning:** All Riellen's Gloves and Copings have dimensionally compatible fittings with the connecting implants: **HE, HI, CM** and **TI**.

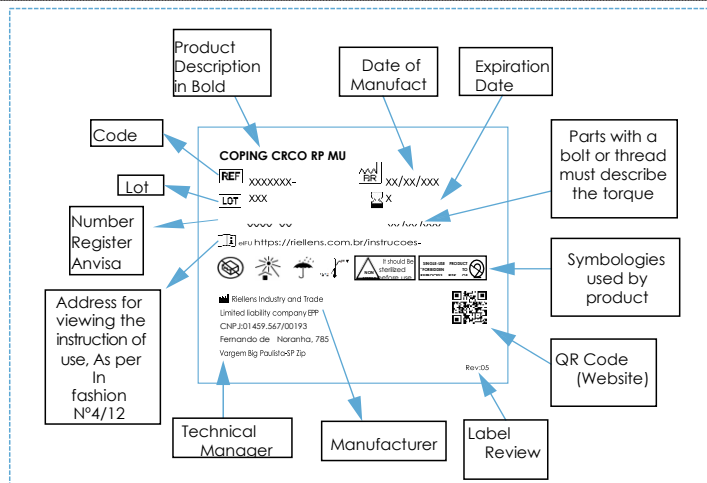
## 3- Specifications and technical characteristics

The Gloves and Copings are available fully plastic, made of Natural Polyacetal and with a CrCo strap, manufactured from Cobalt Chromium according to the Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539) and have a plastic sleeve in a cylindrical shape that is fitted to the top of the base. They are for single use and supplied non-sterile, they come in two pieces, component + screw for fixation.

## 3 - Form of Presentation

### Packing

Riellen's Gloves and Copings are individually packaged in blister packaging ensuring integrity and cleanliness on the product label until the use of the product, information such as: description, dimension, date of manufacture and batch are available on the product label.



**BE CAREFUL WHEN OPENING THE PACKAGE, AVOIDING FALLS, DEFORMATIONS AND ACCUMULATION OF DIRT THAT INTERFERES WITH THE FINAL APPLICATION OF THE PRODUCT.**

## 5- Handling

**Prosthetic:** After the clinical sequence and the preparation of the working model, start the prosthetic planning with the wax-up, defining the final anatomy of the Gloves and Copings. The margins determined by the machining process must be respected. It is not recommended to wax beyond the margins of the components, so that there is no danger of the metal invading the area during the casting process. For fusion coatings, follow the manufacturer's guidelines.

**Dentist:** Prosthesis directly on the implant or in the intermediate - After the completion of the casting process, the prosthesis must be cleaned and sterilized. Place the prosthesis directly on the implant or intermediary and then insert the screw, applying the recommended torque specific to each prosthetic interface, according to the recommended torque table.

## 6- Recommended Torques / Wrenches Used

**Table 2 - Bolt Bolt Matching Table for Sleeve and Coping Components**

COMPONENTS	TYPES OF THREADS	PLATFORM		TORQUE RECOMMENDED	MAXIMUM ALLOWABLE TORQUE	KEY USED		
						HEX. 1.2	UNIG (Torx)	QUAD. 1.3
	Screw thread M1.4	HE	MU(RP); NA (Ø3.0) ES (RP)	20 N.cm	26 N.cm	X	X	X
		HE	HEB (NP)					
	Screw thread M1.6	HI	HI CE (NP, RP, WP, Ø6.0)	25 N.cm	32.5 N.cm	X	X	X
		CM	BL (NC, RP); NA (NP)					
	Screw thread M1.8	HE	MU(WP)	25 N.cm	32.5 N.cm	X	X	X
		HI	MS(Ø3,75)					
		TI	RS (NP)					
		CM	CMN (Ø3.3, 4.5) CMD (Ø3.8)					
	Screw thread M2.0	HE	3HE(NP; WP), HEB (RP)	32 N.cm	41.6 N.cm	X	X	X
		TI	RS (RP, WP, Ø6.0)					
		CM	TL, ST, SI (RN, WN) NA (RP) CMD (Ø4.5/5.0)					
	Screw thread M2.5	HE	HEB (WP)	32 N.cm	41.6 N.cm	X	X	X

## 7- Contraindications

The use of Riellens Gloves and Copings are contraindicated in cases where the patient is sensitive to the material, with the possibility of allergic reactions to any of the chemical elements that make up the raw material, such as:

**Al, Co, Cr, Mo, Ni, Mg, Fe, Si.**

## 8- Adverse Effects

This product has no adverse events as long as it is used correctly for the indicated purposes.

## 9- Sterilization

These products are supplied non-sterile, so they must be sterilized in an autoclave.

- Use chemical and biological indicators for each sterilization cycle, according to the office's protocol
- Allow the products Riellens to dry and cool in the autoclave before handling to avoid contamination.
- Riellens recommends sterilization at 134°C for 15 minutes.
- Riellens recommends placing the components in the proper packaging for autoclave sterilization.

## 10- Precautions and Warnings

Failure to follow the procedures described in this instruction for use may lead to one or all of the following complications: damage to the implant or components; loosening of the components; inadequate final restoration or poor adaptation of the mobile and fixed prostheses; implant failure.

Riellens RECOMMENDS SINGLE USE, AND REPROCESSING IS PROHIBITED, the reuse of the components will result in damage to the health of the patient who may come into contact with a contaminated product. The use of components or instruments that are not compatible will render all warranties void. The correct use and handling of this product is the sole responsibility of the user. Riellens assumes no liability for damages resulting from the incorrect use of its products.

The environment for a Installation of the prosthesis must be clean and suitable for the handling and use of health products.

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**Dental product intended for the use of qualified professionals. Supplied NON-STERILE, never reuse products Riellens, risk of infection with infectious agents.**

## 11-Warnings

Twisting in excess of the recommended torque may result in damage to the bolt fitting and fracture of the bolt. Torsion lower than the recommended torque may result in loosening of the component which may lead to the failure of the prosthesis. Any used component that must be returned to the after-sales service must be sent after cleaning and decontamination in the office.

## 12-Cleaning the components

Prosthetic prostheses should be cleaned, disinfected and sterilized before each use.

- Place the parts in the cleaning bath to remove dirt.
- Use enzymatic detergent, following the instructions for dilution and exposure time determined by the manufacturer.
- Always use distilled or deionized water for this procedure. Heat the water to 30 to 40° for easy cleaning.
- Perform the mechanical removal of dirt from the instruments through manual brushing (brushes with soft bristles or nylon for cleaning fittings).
- Rinse under running water to remove residues and detergents.
- Always dry the instrument using clean soft cloth or use lint-free disposable tissue.
- Pack in specific packages for autoclave sterilization.

Note - The person in charge must be dressed with personal protective equipment (gloves, masks, glasses, aprons, caps, etc.).

## 13- Caution

To tighten the screw, use the torque wrench until the desired torque is obtained, and for stabilization, use the locking wrench. Follow the equipment manufacturer's instructions.

## 14- Post-Installation Care

Advise the patient to periodically visit the dental surgeon.

## 15-Storage conditions

Always store at room temperature between 15°C and 35°C in the original packaging. Do not expose to direct sunlight.

## 16-Disposal of the product

To dispose of Riellens Gloves and Copings used or considered inappropriate, the legal procedures in force for the disposal of products must be followed and must be decontaminated, and may be cut, bent or filed.










## 17- Shelf Life and batch

Date of manufacture, expiration date and batch, see packaging. This product should be discarded if it loses its functionality.

## 15 - WARNING INSTRUCTION FOR USE

This INSTRUCTION FOR USE is made available in non-printed (electronic) format, through the manufacturer's e-mail address [www.riellens.com.br](http://www.riellens.com.br). The INSTRUCTIONS FOR USE are indexed on the website through the respective TRADE NAME of the product, informed on the label of the purchased product. If it is of interest to the professional, the INSTRUCTIONS FOR USE can be provided in printed format, at no additional cost. The request must be made with the manufacturer's Customer Service (SAC).

16-Symbolologies

 REF	Número no catálogo Catalogue number Número de catálogo	 BR	Date of Date of manufacture Fecha de fabricación		Manter Keep dry Mantener seco		Não estéril Non-Sterile No estéril		35°C Limite superior de temperatura Upper limit of temperature
 LOT	Código de Batch code Código de		Válido até Use by Fecha de caducidad		Manter ao abrigo do sol Keep out of the sun Mantener fuera del sol		Consulte as instruções de uso Consult instructions for use/ Consulte las instrucciones de		
	Fabricado por Manufacturer Fabricante		Não utilizar-se a embalagem Do not use if package is No utilizar si el envase está		Não reutilize Do not reuse No lo reutilice		Cuidado Caution Cuidado		15°C Limite superior de temperatura



**RIELLEN'S INDUSTRIA E COMÉRCIO LTDA EPP.**

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