

ATTENTION

The use of Riellens's Healing Agents and Protection Caps are specifically for qualified professionals, with specific training in prosthesis, implantology, including diagnosis, planning and surgical protocol. They are indicated for surgical use. The Healing Agents and Protective Caps supplied by Riellens are available in condition



Not sterile. Never use Riellens Healing Pads and Protective Caps without performing the sterilization process before use.

1 - Intentions of Use

The Healing Agents and Protection Caps have the function of preserving the platform and the interior of the implant, preserving and enlarging, if necessary, the inserted gingiva and adjusting the thickness of the soft tissues, healing the peri-implant gingival tissue.

2 - The indication of the Use

The indication for the use of Healers and Caps is guided according to the following table:

HEALING COMPONENTS / PROTECTIVE CAP										
COMPONENTS	INDICATION FOR USE	CHARACTERISTIC	CONNECTION	DIAMETER	HEIGHTS mm					
					2	3	4	5	6	7
	<p>The Healer and the protective cap are used in the second phase of implant surgery, with the In order to preserve the implant platform, create a cylindrical space in the gum, performing proper healing of the gingival tissue.</p>	<p>It is a single-body component applied directly over the implant</p>	HE	NP, RP and WP	X	X	X	X	X	X
			HI	NP, RP, WP, Ø3.75, 4.1, 4.3, 5.0 and 6.0	X	X	X	X	X	X
			TI	NP, RP, WP and 6.0	X	X	X	X	X	X
			CM	Ø2.9, 3.3, 3.8, 4.0, 4.5, RN, WN, NC, RC, NP, WP	X	X	X	X	X	X
		<p>It is a single-body component applied directly over the intermediate part</p>	HE	NP, RP and WP						
			HI	NP, RP, WP, Ø3.75 and 6.0						
			TI	NP, RP, WP and 6.0						
			CM	2.9, RN, WN, NC, RC, NP and WP						

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

3- Specifications and technical characteristics

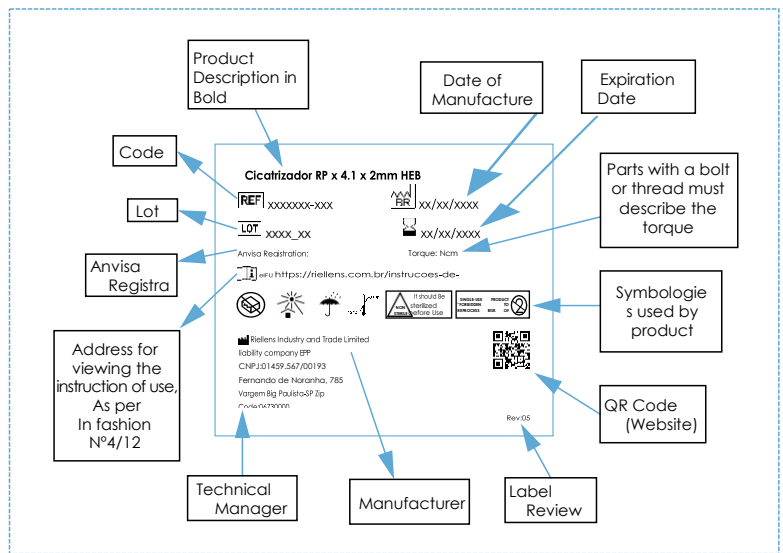
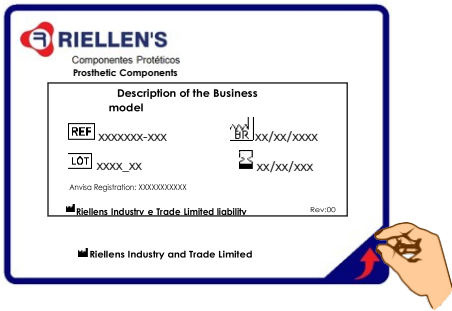
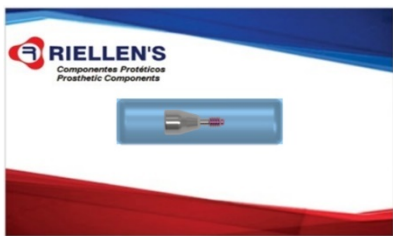
Riellens Healing Agents and Protective Caps are Made of Titanium in accordance with ASTM F136 and ISO 5832-3 (Standard Specification for Wrought Titanium-6Aluminium-4vanadium). They have a cylindrical shape and have a hexagonal fit (1.2mm) or Unigrip at the upper end for the use of instruments and are supplied non-sterile.

4 - Form of Presentation

Packing

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

The Healers and Caps are individually packaged in PET blister packaging with surgical grade paper, ensuring integrity and cleanliness until the use of the professional. Information such as description and fitting are available on the product label.



5- Handling

To open the package, it is indicated, hold the blister firmly and pull out the surgical paper, as shown in the image above. The Healing Agent and the Protective Cap should be used for a short term and it is recommended to remove them within 30 days after installation. For greater safety, protect the surgical field, preventing the product from being swallowed or aspirated by the patient if the product is released into the mouth.

Position the Healing Agent / Protection Cap with the help of a wrench over the implant connection and using a manual torque instrument (torque wrench) apply the recommended torque of 15Ncm, making sure that there are no micro gaps that allow the transit of microorganisms.

6- Contraindications

The use of Riellens Healing Agents and Protective Caps are contraindicated in cases of patients who are allergic to any chemical element that makes up the raw material, such as V, Ti, Ai, O, N, Fe, H and C.

7-Adverse Effects / Technical Complaint

Possible complications: Gum inflammation, localized infections, maladaptation, and mechanical problems.

8- Cleaning the components

Riellens offers all its Wound Healers and Protective Caps Sanitized.

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 Riellens Healers/Protective Cap 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

- The use of non-compatible components or instruments 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 damage resulting from the incorrect use of its products. The environment for the installation of the prosthesis must be clean and suitable for the handling and use of health products
- It is **'FORBIDDEN to REPROCESS'** the Healers and Protective Caps, the reuse of the components will result in damage to the health of the patient who may come into contact with a contaminated product.
- Twisting in excess of the recommended torque may result in fitting damage, fracture, or locking of the Healers and Protective Caps causing implant failure. Twisting less than the recommended torque may result in loosening of the component than Canlead a Badcicatrization of the fabric Gum.

ATTENTION

Dental product intended for use by qualified professionals. Supplied NOT STERILE, never reuse Riellens Healing Pads / Protective Caps risk of infection with infectious agents. Caution when handling the component risk of accidentally aspirating or swallowing.

11-Adverse Effects

- If there are any technical complaints or adverse events with Riellens products, please notify us through Customer Service.
- Ensure that the Healers and protective caps are correctly aligned to avoid wear on the threads.
- In the event of damage to the blister pack or after the expiry date, Riellens Wound Healers and Protective Caps cannot be used.
- Any used component that must be returned to the after-sales service, must be sent sterile after pre-disinfection, cleaning and decontamination in the office.

12- Storing Conditions

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

13- Product Disposal

To dispose of the Healing Agents and Protective Caps used or considered inadequate, the legal and current procedures for the disposal of products must be followed and must be decharacterized. They can be cut, bent or filed.

14- Shelf Life and Batch

Date of manufacture, expiration 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 electronic address 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 product purchased. 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- Symbologies

 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
 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		Limite superior de temperatura Upper limit of temperature Limite superior de temperatura



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