

ATTENTION

The use of Riellen's Pillars is 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. Abutments supplied by Riellens are available in **Non-Sterile condition**. Never use Riellens Products without carrying out the sterilization process.

1 - Intentions of Use

Riellens Abutments and Mini Abutments attach partial or total dentures to the implant in order to replace or replace the tooth structure and re-establish the patient's masticatory and aesthetic functions.

2 - The indication of the Use

The indication of the use of the Pillar is guided by the following table:

COMPONENTS	TEMPLATES	INDICATIONS FOR USE		COMPATIBLE WITH IMPLANT SYSTEM	PLATFORM	HEIGHTS mm					
						1	2	3	4	5	
	Mini Conical Abutment	Used in the manufacture of single screwed prostheses or with more than one element (Multiple), being fixed directly to the implant.		HE HI	NP, RP, WP NP, RP, WP						
	Mini Conical Abutment Ang 17° and 30°	Used in the manufacture of single screw-retained prostheses or with more than one element (Multiple), with the need to correct the inclination of the implant with an angle of 17° and 30°, being fixed directly to the implant.		TI CM	Ø 3.75, NP, RP, WP Ø 3.5, Ø 3.8, Ø 4.5, NN, NP, RN, RP, WN	X	X	X	X	X	
	Conical Abutment	Used in the manufacture of single screwed prostheses or with more than one element (Multiple), being fixed directly to the implant.		HE HI	NP, RP, WP NP, RP, WP						
	Conical Abutment Ang 17° and 30°	Used in the manufacture of single screwed prostheses or with more than one element (Multiple), with the need to correct the inclination of the implant with an angle of 17° and 30°, being fixed directly to the implant.		TI CM	Ø 3.75, NP, RP, WP Ø 3.5, Ø 3.8, Ø 4.5, NN, NP, RN, RP, WN	X	X	X	X	X	
	Abutment Interface / Ti base	Used in the manufacture of single or multiple cemented prostheses specific for CAD/CAM systems being attached directly to the implant.	Anti-Rotational Rotational	Used for single prosthesis Used for prosthesis with more than one element (Multiple)	HE HI TI CM	NP, RP, WP Ø 3.3, Ø 3.7, Ø 3.75, Ø 4.2, Ø 4.5, NP, RP, WP Ø 3.3, NP, RP Ø 3.3, 3.5, 3.8, 4.5, NP, RN, RP, WN	X	X	X	X	X
	Provisional Abutment	Used in the manufacture of a temporary cemented prosthesis, it must be prepared in the laboratory before its use.	Anti-Rotational Rotational	Used for single prosthesis Used for prosthesis with more than one element (Multiple)	HE HI TI CM	- NP, RP, WP Ø 4.1, 4.3, 5.0, NP, RP, WP Ø 3.3, NP, RP	-	-	-	-	-
	Abutment	Used in the manufacture of permanent cemented prosthesis with more than one element (Multiple), being fixed directly to the implant.			Ø 3.0, NN, NP, RN, RP, WN						
	Abutment Ang	Used in the manufacture of single and multiple permanent cemented prosthesis, with the need to correct the inclination of the implant with an angle of 17° being fixed directly to the implant.									
	Provisional Immediate Abutment	Used in the manufacture of a temporary cemented prosthesis with more than one element (Multiple), and can be used immediately without the need for preparation. One-piece with hexagonal external fitting, where the digital key is inserted to give the torque.				X	X	X	X	X	
	Solid Abutment	Single-body piece. Used in the manufacture of permanent cemented prosthesis with more than one element (Multiple), being fixed directly to the implant.	CM	RN, WN		-	-	-	X	X	

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

Warning: All Riellens Abutments/Mini Abutments have dimensionally compatible fittings with the connecting implants: **HE, HI, CM** and **TI**.

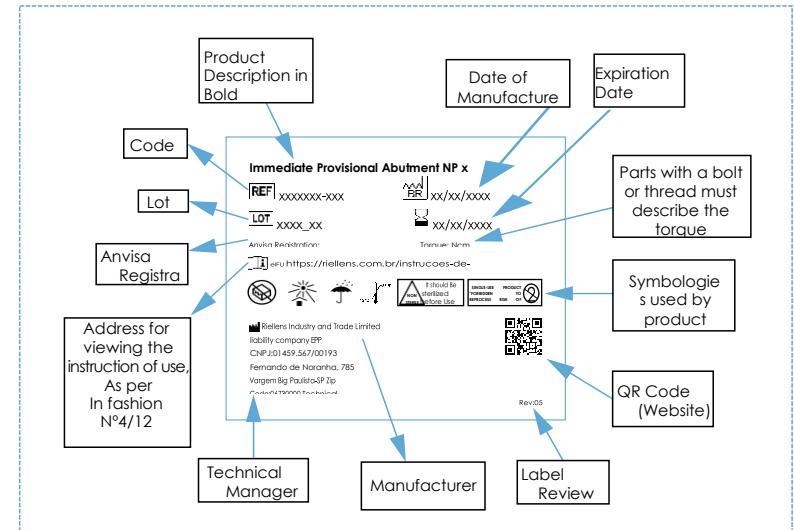
3- Specifications and technical characteristics

Riellens Abutments and Mini Abutments are manufactured by the machining process, in titanium according to ASTM F136 and ISO 5832-3 standards (Standard Specification for Wrought Titanium- 6Aluminum-4Vanadium), have a cylindrical shape, are single-use and supplied non-sterile.

4-Form of Presentation

Packing

The Pillars and Mini Pillars Riellens are individually wrapped in blister packaging ensuring a Integrity and cleanliness on the product label until use of PROfiSSional, 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- Recommended Torques / Wrenches Used

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

SCREWS AND ABUTMENTS	INDICATIONS FOR USE	TYPES OF THREADS	PLATFORM	TORQUE RECOMMENDED	MAXIMUM TORQUE ALLOWED	KEY USED		
						HEX 1.2 (Torx)	UNIGRIP 1.3	QUAD. 1.3
	They are indicated for fixing the components directly to the implant, with the application of controlled torque ensuring the perfect adaptation. They are made with ASTM F136 Titanium in a single body with an external thread at one end and an internal fitting in the shape of Hexagonal, Square or Unigrip at the other.	Screw thread M1.4	RP, WP, Ø 3.0	20 N.cm	26 N.cm	X	X	-
		Screw thread M1.6	NC, NP, RC, RP, WP, Ø 3.3, Ø 3.5/4.0, Ø 4.1, Ø 4.3, Ø 5.0	25 N.cm	32.5 N.cm	X	X	-
		Screw thread M1.8, M2.0, M2.5	NP, NN, RP, RN, WP, WN, Ø 3.7, Ø 3.75, Ø 3.8, Ø 4.2, Ø 4.5, Ø 4.5/5.0	32 N.cm	41.6 N.cm	X	-	X
	They are indicated for fixing the components directly to the implant, with the application of controlled torque ensuring the perfect adaptation. They are made with ASTM F136 Titanium in a single body, having an external thread at one end and an internal fitting in the shape of Hexagonal, Square or Unigrip at the other end.	Specific for Mini Conical Abutment and Conical Abutment with M1.6 thread	NP, RN, RP, WN, WP, Ø 3.5/4.0, Ø 4.1, Ø 4.3, Ø 5.0	20 N.cm	26 N.cm	For Mini Abutment / Immediate Temporary		
						X	-	-
						-	X	-
						X	-	-
	Immediate Provisional Abutment Used in the manufacture of a temporary cemented prosthesis with more than one element (Multiple), and can be used immediately without the need for preparation. One-piece with hexagonal external fitting, where the digital key is inserted to give the torque.	M1.6 and M1.8 thread	NP, RP, WP, Ø 4.3, Ø 5.0	25 N.cm	32.5 N.cm	X	-	-
		M2.0 and M2.5 thread	NP, RP, WP	32 N.cm	41.6 N.cm	X	-	-

6-Handling

Clinical procedure after the prosthetic process

Screwed Prosthesis:

- 1.Clean and disinfect the final restoration, as instructed by the restorative material manufacturer.
2. Remove the scar or temporary restoration from the patient.
3. Connect and fasten the hard reset with a digital key. It is recommended to check the adaptation of the Abutment using radiographic images.
4. Tighten the Abutment with the torque wrench, applying the recommended torque, as shown in the Table.

Cemented prosthesis:

- 1.Clean and disinfect the final restoration, as instructed by the restorative material manufacturer.
- 2.Remove the healer or temporary restoration from the patient.
3. To cement the metal pillars with the prosthesis, use the cement according to the amount indicated by the manufacturer of the restorative material:

Definitive Cementation: Zinc Phosphate.

Temporary Cementation: Calcium hydroxide.

7-Contraindications

The use of Riellens Abutments and Mini Abutments are contraindicated for patients with insufficient bone height/width to obtain safe support in functional loads, smokers, patients with parafunctional habits, e.g. Bruxism and patients who have allergy to any chemical element that makes up the raw material such as: **V, Ti, Al, O, N, Fe, H and C.**

8-Cleaning the components

Abutments/Mini Abutments 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.).

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 Abutments 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 any or all of the following complications: damage to the implant or components; loosening of components; inadequate final restoration or poor adaptation of 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 the installation of the prosthesis must be clean and suitable for the handling and use of health products.

ATTENTION

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

11-Warnings

Applying more torque than recommended can cause damage to the bolt fit, resulting in fractures or component locking.
Applying less torque than recommended may result in loosening of the component.

Failure to apply the recommended torque may lead to prosthesis failure.

The use of components that have corrosion characteristics can cause toxic effects to the patient.

Possible complications:

Pain, peri-implant mucositis, peri-implantitis, aesthetic problems.

12- Caution

To tighten the screw, use the calibrated torque wrench until the recommended torque is obtained and for stabilization, use the locking wrench according to table 2. Follow the torque wrench manufacturer's instructions.

Ensure that the connecting screws between the implant and the abutment are correctly aligned on all secondary components to avoid wear on the threads.

Excess cement left on inadvertently is a major problem and can result in soft tissue damage, plaque buildup causing chronic inflammation. (Peri-implant)

When used intraorally, the products should be protected against any risk of swallowing or aspirating. Protect the components (e.g. with a throat pack or dental floss).

13-Storage conditions

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

14- Post-Installation Care

Advise the patient to periodically visit the dental surgeon.

15-Disposal of the product

To dispose of Riellens Pillars/Mini Pillars used or considered inadequate, the legal procedures in force for the disposal of products must be followed and must be deacterized, and they can be cut, bent or filed.

16- Shelf Life and Batch

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

17 - 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. 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).

18- Symbolologies

REF	Número no catálogo Catalogue number Número de catálogo		Date of manufacture Date of manufacture Fecha de fabricación		Mantener Keep dry Mantener seco		Não estéril Non-Sterile No estéril		Límite superior de temperatura Upper limit of temperature Límite superior de temperatura
LOT	Código de Batch code Código de		Válido até Use by Fecha de caducidad		Mantener 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		Cuidado Caution Cuidado
	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				O dispositivo não apresenta perigos conhecidos em um ambiente de MR especificados com condições específicas de uso Device poses no know hazards in a specified MR environment with specified conditions of use El dispositivo no presenta peligros conocidos en un entorno de MR especificado con condiciones específicas de uso



RIELLEN'S INDUSTRIA E COMÉRCIO LTDA EPP.
Rua: Fernando de Noronha, 785 - Jardim Margarida

CEP: 06730-000 - Vargem Grande Paulista/SP - Brasil
CNPJ. 01.459.567/0001-93 AUTORIZ/MS: 8.05237.8

SAC / Consumer Attendance Service:

55 11 4158 - 9218 / 55 11 4158-5018

e-mail: sac@riellens.com.br

Resp. Técnica/ Technical Responsible / Resp. Técnica:

Bruna Fernanda Marcelino Silva Queiroz

CRFSP nº / Professional ID.: 100327

Registro ANVISA nº. / ANVISA Registration nº.: Mini Abutment Nº 80523780006 /
Abutment Nº 80523780008