

ATTENTION

Riellens Instruments are specifically for use by qualified dentists with specific training in implant dentistry, including diagnosis, preoperative planning, and surgical protocol. The Instruments supplied by Riellens are made available in **a non-sterile condition, subject to reprocessing, and must be sterilized before each use.**

1 - Intentions of Use

Riellens Instruments have the function of assisting in the installation or removal of components and implants.

2 - The indication of the Use

The indication of the use of the Instrumentals is guided according to the following table:

Keys	Indication for Use	Model	Description	Size	Maximum Torque		
	Used for capturing, transporting, fixing and removing screws and prosthetic components.	Digital Key	Hex Digital Wrench 0.9	Short, Medium and Long	15 Ncm		
			Digital Screwdriver Hex Digital Wrench 1.2 Square Digital Key Unigrip Digital Wrench Torx Digital Wrench		41,6 Ncm		
		Mini Tapered Pillar Digital Key Hexágono 2.0mm Mini Tapered Pillar Digital Key Hexágono 2.5mm	-	-			
		Torque Wrench	Hex Torque Wrench 0.9	Short, Medium and Long	15 Ncm		
Hex Torque Wrench 1.2 Square torque wrench Unigrip torque wrench Torx torque wrench Quad adapter for torque wrench			41,6 Ncm				
Mini Pillar Hexagon Torque Wrench 2.0mm Mini Pillar Hexagon Torque Wrench 2.5mm			-		-		
		Counter angle wrench	Hex Counter Angle Wrench 0.9	Short, Medium and Long	15 Ncm		
			Hex Counter Angle Wrench 1.2 Square Counter Angle Wrench Unigrip Counter Angle Wrench Dynamic Contra-Angle Switch		41,6 Ncm		
  		Used for capture, transport, extraction and fixation of the implant	Insertion Wrench	Insert Key 3.0; NP and RP NA Insert Key NP, RP and WP HE Insert Key NP, RP and WP AT Insert Key 3.0, NC and RC BL Insert Key MS Insert Key CMN	Short, Medium and Long	45 N.cm	
			Assembler	Zygomatic assembler 45° HE Zygomatic assembler 0° HE			-
	Extractor		Implant Extractor NP/RP	-			-

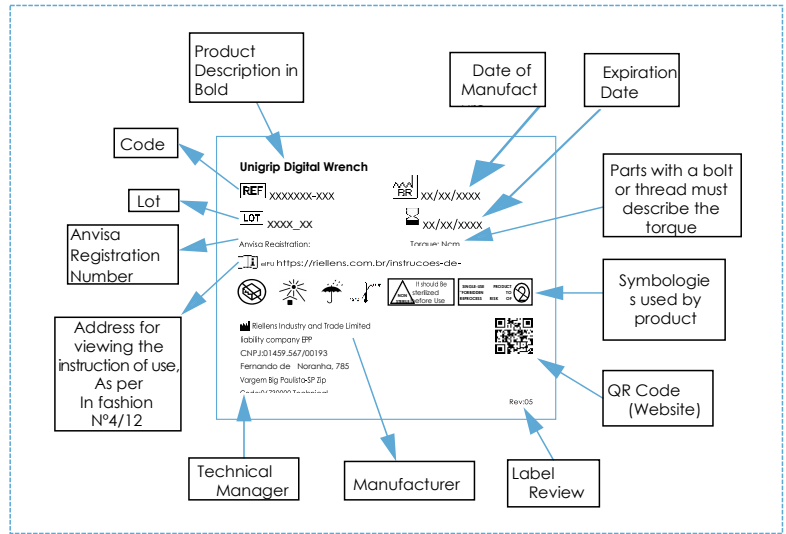
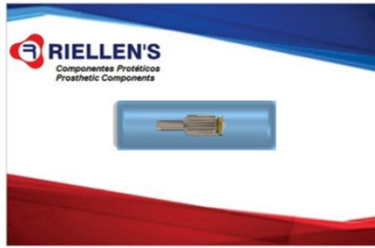
3- Specifications and technical characteristics

Riellens Instruments are manufactured in ASTM F899 (Standard Specification for Wrought Stainless Steels for Surgical Instruments) ISO 5832-1 (Standard Specification for Implants for Surgery – Metallic materials Wrought Stainless Steels) with Titanium Nitride (TiN) coating that increases resistance to wear and corrosion, have a cylindrical shape, are reusable and supplied non-sterile.

4-Form of Presentation

Packing

The Riellens Instruments are individually wrapped in blister packaging, ensuring a integrity and cleanliness of the product until professional use. Information such as: description and fitting, 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

To open the package, it is recommended to hold the blister firmly and pull out the surgical paper, as shown in the image above. To use the wrench, fit the wrench tip into the hex, square, or Unigrip inner socket of the screw or prosthetic component and then apply recommended torque to each component or implant. For added safety, pass a dental floss through the hole in the ring on the digital key, or make sure that the key is well fixed in the counter-angle, avoiding the release of the product inside the mouth, ensuring that the parts are not swallowed or aspirated by the patient.

6-Contraindications

This product has no contraindications, as long as it is used correctly for the purposes indicated.

7- Adverse Effects / Technical Complaint

Possible adverse effects: Rare cases of sensitization (allergy) and irritation may occur with patients who are sensitive to the composition of the product.

8- Cleaning the Instruments

Instruments should be cleaned, disinfected, and sterilized before each use.

- Cleaning, disinfection and sterilization of the key should only be done by well-trained and qualified personnel for these operations, following protocols for product reprocessing.
- Place the parts in the cleaning bath to remove the organic matter from the instruments as soon as possible after use;
- Use enzymatic detergent, following the dilution and exposure time instructions determined by the manufacturer.
- Always use distilled or deionized water for this procedure. Heat the water to between 30 and 40°C 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 tissue or use lint-free disposable tissue .
- Pack in specific packaging for autoclave sterilization.

Note - The person in charge must be dressed with personal protective equipment (gloves, masks, goggles, 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 Riellens instruments to dry and cool in the autoclave before handling to avoid contamination and oxidation of the material.
- Riellens recommends sterilization at 134°C for 15 minutes.
- Riellens recommends placing the instruments 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.
- Riellens instruments come into contact with the oral mucosa, so there is a risk of biological contamination and transmission of infectious diseases, never use without carrying out the cleaning, disinfection and sterilization process before each use.
- Torsion exceeding the maximum torque may result in fracture or deformation of the instrumental, implant and/or screw, impairing the progress of the treatment.

ATTENTION

Dental product intended for use by qualified professionals.

Supplied NON-STERILE, never use Riellens instruments without carrying out the cleaning and sterilization process after each use, risk of infection with pathogens.

Caution when handling the instrumental, risk of accidentally aspirating or swallowing, can lead to damage to the digestive and respiratory tract.

11- Warnings / Caution

If you experience technical complaints or adverse events with Riellens products, please notify us through Customer Service.

- Never use acids (hydrogen sulphide, nitric acid, hydrochloric etc.), saline solutions, especially sodium hypochlorite and saline solution for cleaning or rinsing surgical instruments, to avoid the corrosion process.
- It is recommended to follow the moist heat sterilization method through the use of an autoclave, following the parameters and procedures set forth in this instruction for use and ISO 17665-1.
- Never use steel wool or sponges and abrasive products, so that the instruments are not damaged.
- Avoid friction between instruments in cleaning, to avoid deformation of smaller and delicate parts.
- Never allow the instrument to dry naturally, humidity favors corrosion of the material.
- Never overlap the instruments on the autoclave, it may affect the effectiveness of sterilization.
- The sequential and correct use of the keys reduces the possibility of damage to the products and allows the correct technique of insertion and installation of the implant and components.
- 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-Lifespan

Do not use the instrument if you notice cracks, wear, or oxidation/corrosion points. This can cause problems in the performance of the instruments and increase the risk of bacterial proliferation. This product is recommended for up to 30 uses, as long as the conditions of use recommended by Riellens are respected. Regardless of the number of times the instrument has been used, the professional should always evaluate its condition after each use.

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-Disposal of the product

After the end of the life of the instrumental it should be discarded. To dispose of the instruments used or considered inadequate, the legal and current procedures for the disposal of products must be followed and must be decharacterized, and may be cut, bent or filed.

15- Shelf Life and Batch

Expiration date and batch, see packaging. The expiration date described on the label is equivalent to the period that Riellens guarantees its hygiene in the original packaging and not after use, this product must be discarded if it loses its functionality, or as described in item 12 Shelf Life.

16 - 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).

17-Symbologies

 REF	Número no catálogo Catalogue number Número de catálogo	 BR	Data de Fabricação Date of manufacture Fecha de fabricación		Manter seco Keep dry Mantener seco		Devendo ser esterilizado antes do uso Non-Sterile No estéril
 LOT	Código de lote Batch code Código de lote		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 uso
	Fabricado por Manufacturer Fabricante		Não utilizar se a embalagem danificada Do not use if package is damaged No utilizar si el envase está dañado		Produto de uso único Single-use Product Producto de un solo uso		35°C Limite superior de temperatura Upper limit of temperature 15°C Limite superior de temperatura



RIELLEN'S INDUSTRIA E COMÉRCIO LTDA EPP.

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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 n° / Professional ID.: 100327

Registro ANVISA n° / ANVISA Registration n°.: Instrumental 80523780001 /
Prosthetic Kit N° 80523790001