RIELLEN'S

# PRACTICAL GUIDE

Techniques for use, cleaning and sterilization of Riellens products, including information on magnetic resonance MRI

Welcome!

Here you will find the Techniques Guide for use, cleaning and sterilization, including MRI information for Riellens products.

## Certificates

Riellens complies with ISO 13485 and RDC 16 Anvisa Good Manufacturing Practices for Medical Products.

CERTIFICAÇÃO BPF
BOAS PRATICAS DE FABRICAÇÃO E CONTROLE DE PRODUTOS PARA SAÚDE

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# Purpose of this document and general information

## Purpose of this document

This document provides general guidelines for qualified dentists informing the procedures for correct handling of the medical devices supplied by Riellens. The products guarantee the integrity and cleaning of the product until professional use. It also provides inspection guidelines to determine when an instrument has reached the end of its useful life and must be replaced and MRI information.

## General information

The applicability of these guidelines for Riellens devices is indicated on the respective labels and in the instructions for use (IFU), where applicable. For detailed explanations of the symbols, see page 7 of this guide.

Riellens has demonstrated that the process described in these cleaning, disinfection and sterilization guidelines are efficient and that the devices are compatible with the methods described. The guidelines are based on validated processes. It is recommended to follow these instructions to avoid negatively affecting the performance of the products. Whenever the instructions for use of a specific product show other conditions of the procedure, these will replace the recommendations given in these general guidelines.

As far as conflicting national cleaning and sterilization requirements are concerned, these must prevail over Riellens' recommendations.

Operators, equipment, and cleaning procedures contribute to the effectiveness of the process. 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.

The information about Riellens components that are subject to contact with MRI magnetic resonance environments is intended to provide the data necessary for radiologists to make safe diagnoses.

**Note:** According to the standard Sterilization of health care products - Information to be provided by the manufacturer for processing of resterilizable health care products EN ISO 17664, it remains the responsibility of the user to ensure that proper equipment, materials and personnel are used in a possible reprocessing, in order to avoid undesired results. Likewise, any deviation due to inadequate assessment by the professional can cause adverse consequences to the patient. Riellens RECOMMENDS SINGLE USE.

YOU MUST NOT RESTERILIZE the products.

# Terms and Definitions

To avoid misunderstanding of the most commonly used terms, the meaning of each of these terms within this document are listed below:

**Cleaning**

Removal of visible dirt; it is usually carried out manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before disinfection and sterilization, as inorganic and organic materials remain in the processes described.

After cleaning, no visible contamination should be found in an inspection with the naked eye under good light conditions.

**Decontamination**

Removal of pathogenic microorganisms from objects so that the devices are safe to handle, use or discard.

**Disinfection**

A process that kills most disease-producing microorganisms, but not necessarily all microbial forms (for example, bacterial spores).

**Sterilization**

A validated process used to make a viable microorganism-free product.

**Validation**

Documented procedure for obtaining, recording and interpreting the results necessary to establish whether a process will be consistent in manufacturing health care products in accordance with predetermined specifications.

**Autoclave**

It is a device used to sterilize products by moist heat under pressure using high temperatures.

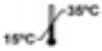
Note: In a sterilization process, the nature of microbial death is described by a mathematical function. Therefore, the presence of microorganisms in any particular product can be reduced to a very low number, but can never be reduced to zero. This probability can only be assured by validated processes.

Sterility Assurance Level (SAL): Probability of a single viable microorganism out of 1,000000 in an item after sterilization. The term SAL takes a quantitative value, usually 10-6.

# Abbreviations

| | |
|---|---|
| **°C** | Degrees Celsius |
| **°F** | Degrees Fahrenheit |
| **ASTM** | American Society for Testing and Materials |
| **EN** | European Standard |
| **IFU** | Instruction for Use |
| **MRI** | Magnetic Resonance Imaging |
| **SAL** | Sterility Assurance Level SAL: probability of a single microorganism |

# Explanation of symbols on labels and instructions for use

| | |
|---|---|
|  | Fabricante / Manufacturing / Fabricante |
|  | Data de fabricação / Date of manufacture / Fecha de fabricación |
|  | Referência de catálogo / Catologue number / Número de catálogo |
|  | Código do lote / Batch code / Código del lote |
|  | Prazo de validade / Use by / Fecha de caducidad |
|  | Cuidado / Caution / Cuidado |
|  | Consulte as instruções de uso / Consult instructions for use / Consulte las instrucciones de uso |
|  | Não reesterilize / Do not resterilize / No reesterilice |
|  | Mantenha afastado da luz solar / Keep away from sunlight / Mantener fuera de la luz solar |
|  | Não reutilize / Do not reuse / no lo reutilice |
|  | Não utilize se a embalagem estiver danificada / Do not use if package damaged / No utilizar si el envase está dañado |
|  | Limite Superior de temperatura / Upper limit of temperature / Limite superior de temperatura |
|  | Não estéril / Non-Sterile / no estéril |
|  | Conserve seco / Keep dry / Mantener seco |
|  | O dispositivo não apresenta perigos conhecidos em um ambiente de MR especificado com condições especificas de uso / Device poses no known 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 especificas de uso |

# Information on Magnetic Resonance Imaging (MRI)

The following definitions of safe MR and conditional MR were developed by the American Society for Testing and Materials (ASTM) International.[1]
This section is intended to provide the MR symbol and other MR related information.

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**MR Safe**
Items that do not pose known risks in all MRI environments are labeled MR Safe. This includes all Riellens products that are non-conductive, non-metallic and non-magnetic. Examples are copings and plastic gloves.


Items marked with the MR safe icon can be taken, used, or placed anywhere within any MRI environment without causing any additional risk to the patient or any other individual.

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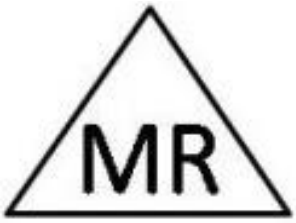
**MR Conditional**
Items that have been shown to pose no known hazards in a specified MRI environment with specified conditions of use are labeled MR condition.
A patient with this device can be safely checked after placement under the following conditions:
- Static magnetic field 1.5-3.0 Tesla
- Maximum spatial gradient magnetic field of 4000 Gauss / cm (40 T / m)
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 4 W / kg (first level controlled mode)
Normal operating mode of the MR system




1 American Society for Testing and Materials, Designation: F2503. Standart Practice for Marking Medical Devices and Other items for Safety in the Resonance Environment. ASTM International, 2005.

**Heating related to magnetic resonance**

In worst-case non-clinical tests, some metallic Riellens products caused the following rise in maximum temperature during 15 minutes of MRI with 1.5 and 3.0 Tesla.

The elevated temperature poses no known hazard to the patient.

| | **1.5 Tesla** | **3.0 Tesla** |
|---|---|---|
| | 64 MHz | 128 MHz |
| Maximum MR system, the whole body was calculated | 4 W/Kg | 4 W/Kg |
| Measured calorimetry values, total body average | 2.1 W/Kg | 2.7 W/Kg |
| Biggest temperature change (all tests) | + 4.1°C | + 2.9 °C |
| Maximum spatial gradient magnetic field | 4000 W/Kg | 4000 W/Kg |
| Test System | Magnetom (active shielded field, horizontal) | Excite, HDx |
| | *Software Numaris/4, Version Syngo MR 2002B DHHS | Software 14X.M5 |
| | Siemens Medical Solutions, Marvern, PA, EUA | General Electric Healthcare, Milwaukee, WI, USA. |

**Information on artifacts**

The quality of the MR image may be compromised if the area of interest is in the same area or relatively close to the position of the MR-conditional device. It may therefore be necessary to optimize the MR imaging parameters to compensate for the presence of the device. The artifact's maximum size (as seen in the gradient echo pulse sequence) extends to approximately 30mm in relation to the device's size and shape.

| **Pulsed sequence** | **T1-SE*** | **T1-SE** | **GRE**** | **GRE** |
|---|---|---|---|---|
| Flat orientation | Parallel | Perpendicular | Parallel | Perpendicular |
| Signal empty size *** | 2754 mm2 | 2229 mm2 | 4458 mm2 | 5463 mm2 |

* T1-SE: longitudinal relaxation, spin echo sequence

** GRE (low angle of inclination): gradient-echo MRI sequence

*** Maximum empty size found in all tests

**Notes:**

- Removable restorations must be removed before scanning, as is done with watches, jewelry, etc.

- Polymeric (e.g. PEEK) and ceramic devices are considered MR safe; however, one should be classified according to the component with the lowest safety level.

# 1. Use

**Technique for use:**

Modifications to the Abutments can be carried out with abundant water irrigation. Extra-oral modification of the abutment is recommended.

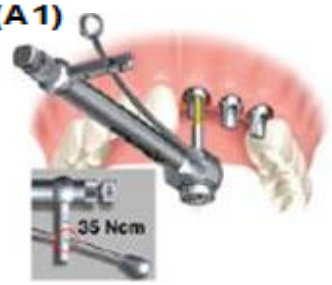
Clinical procedure:

1. Select the appropriate abutment and check the occlusal clea

2. Connect and tighten the Abutment. It is recommended to check the final abutment seating using radiographic ima

3. Tighten the Abutment with the appropriate wrench, according to figures (A1) and (A2). Recommended Torques/Wrenches used Abutment/Mini Abutment x Wrench are located in the product's Instruction for use.

(A1)



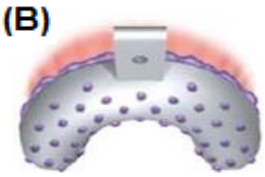

(A2)


**Caution:** for all connection types never exceed the prosthetic tightening torque indicated in the product's instructions for use. Over-tightening the Abutment/Mini Abutment may lead to a screw fracture.

4. Modify the abutment, if necessary, using abundant irrigation

5. Take a standard impression, following protocol for open or closed tray.

(B)



6. Reline after sealing the access hole. Make sure there is no excess cement.

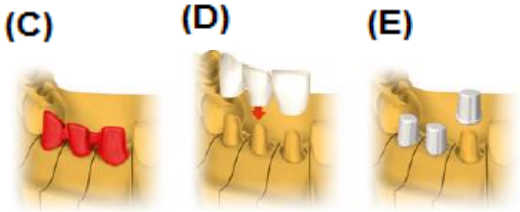
**Caution:** Do not use plastic temporary coating material with cemented polyurethane.

Laboratory procedure:

7. Produce a working model with removable gingival material

8. Prepare a crown or bridge with the conventional casting technique (C + D). For the Esthetic Abutment, plastic copings can be used as casting patterns (E)

(C) (D) (E)



Note: For temporary prosthesis use calcium hydroxide-based cement and for permanent prosthesis use zinc phosphate-based cement.

9. Cement the crown or framework, if applicable.

Clinical procedure:

10. Remove the temporary restoration, if applicable

11. Cement the final crown to the framework using conventional access hole procedures (F).

Make sure that there is no excess cement.

(F)

Note: Use the cement according to the quantity indicated by the manufacturer.

**Caution:** Temporarily not cementing when cementing ceramic crowns and bridges can increase the risk of micro-fractures.

# 2. Cleaning

## Mechanical cleaning procedure

### Equipment needed

Ultrasonic Washer - Converts ultra-high frequency sound waves into mechanical vibrations, which move in the water creating microscopic bubbles. Ideal for inaccessible internal spaces for direct rubbing and recesses.

Ultrasonic bath large enough to allow complete immersion of products, frequency 25-50 KHz, temperature according to the detergent manufacturer's instructions.

If, after completion of the cleaning step in the ultrasonic bath, there is dirt embedded in the product that has to be removed with the brush, the cleaning step should be repeated as mentioned above.

### Manual cleaning procedure

Products must be cleaned, disinfected, and sterilized before each use.

Place the parts in the cleaning bath to remove organic matter as soon as possible after use; remove dirt from the components by manual brushing (brushes with soft bristles); use enzymatic detergent, following the instructions for dilution and exposure time determined by the manufacturer, meeting the criteria indicated on page 15 of this guide and concentration as specified in the detergent manufacturing instructions. Rinse under running drinking water to remove residues and detergents. Always dry the component using soft, lint-free disposable cloth.

**Note:**

The cleaning procedure is indicated for products that can be reprocessed, that is, reusable, such as: Analog, transfer, and wrenches.

**Warning:**

Avoid mechanical damage, do not mix heavy and delicate devices. Pay special attention to the cutting edges, both to avoid injury and to prevent damage to medical devices.

# 3. Sterilizing

Riellens products are not sterile, so they must be sterilized in an autoclave at the Sterile Material Center (SMC) of the office, according to professional protocol and manufacturer's instructions, before being used on the patient.

The sterilization process aims at the total elimination of microorganisms (viruses, bacteria, microbes, and fungi). The products already packed and properly identified must be sent to Auto Clave (follow the instructions for use according to the equipment manufacturer's manual).

**Packaging**

Riellens recommends that for the product to be sterilized in the autoclave it should be repackaged and identified with the product description, lot and date of sterilization. The products must be placed one by one in a self-adhesive surgical grade paper envelope for steam sterilization in an autoclave, and it is forbidden to resterilize Riellens Abutments and Healers.

Figure 1 - Performing the repackaging process

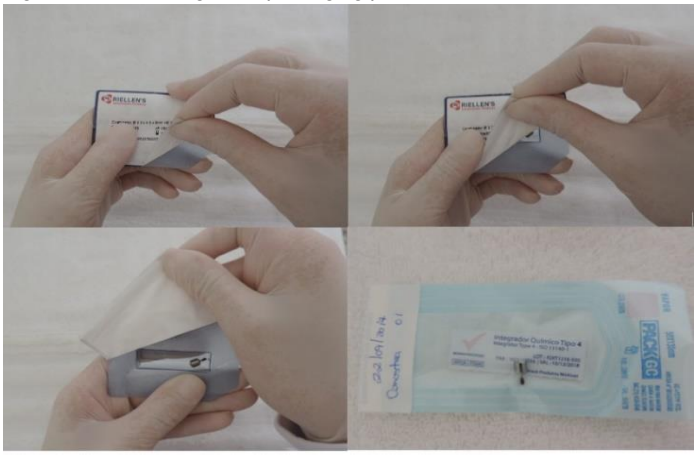


Figure 2 - Autoclavable packaging

**Arrangement of Products in the Autoclave**

Remove the inner basket from the chamber with the shelves and mount the load outside the equip

Place the products to be sterilized in the chamber, do not remove the shelves (the product must be of a size compatible with the storage capacity of the shelves). Placement in the autoclave must be done so that the steam can circulate freely and pass through the entire packaging. The products must be positioned so that the paper is facing up.

Figure 3 - Arrangement of Products in the autoclave

**Parameters for autoclaving:**

The products already packed and properly identified must be sent to Auto Clave (follow the instructions for use according to the manufacturer's manual). The parameter used for sterilization is 134 °C +/- 1 °C for 18 minutes; this temperature guarantees the effectiveness of the sterilization without damaging the product.

**Biological indicators**

Riellens recommends controlling the sterilization effectiveness in the autoclave by performing a control test once a week or at least every 30 days. The resistant spore population is inoculated on a strip of paper inside a thermoplastic bottle that serves as a culture flask. Also contained in the bottle is a small breakable glass ampoule containing culture medium of the Biological indicator - Bacillus stearothermophilus ATCC 7953. The indicators must be incubated for a maximum of 3 hours after sterilization, respecting the reaction time, which can vary from 24 to 48 hours.

Once correctly incubated, the medium color changes to yellow, when there are viable spores and sterilization has been ineffective. As soon as a control turns yellow, it must be properly recorded and then autoclaved and discarded. The process is only effective when the medium does not change color.

Figure 4 - Biological indicator bottle

**Preventive maintenance of the equipment (Autoclave)**

**Daily:**

- Clean the chamber and door seal gasket
- Check the condition of the door lock

**Weekly:**

- In addition to the previous iten
- Change the distilled water contained in the reservoir and perform an internal clean

**Monthly:**

- In addition to the previous iten
- Clean and unclog the filters and valves;
- Check and retighten the electrical system's contacts and hydraulic connections
- Carry out a test run of the safety valve, pulling its lug five times.

**Semiannually:**

- In addition to the previous iten
- Clean and unclog the pipes and hydraulic components;
- Check the door closing system.

**Annually:**

- In addition to the previous iten
- Adjust the water flow rate of the vacuum pump;
- Perform the calibration of the protection and control instruments;
- Perform the validation of the safety and control elements;
- Adjust the door closing system;
- Check grounding conditions and quality
- Carry out the test and hydrostatic assessm

**Warning:** Use of non-sterile products can lead to tissue infection or infectious diseases

# 4. Storage / Handling

To store the products after sterilization, the autoclavable packages should be properly stored so as not to compress them, not twist them, not perforate them so as not to compromise their sterility, keeping them away from moisture, at a distance of 25cm from the floor, 45cm from the ceiling and 5cm from the walls. Ideally, it should be stored on a shelf or closed cabinet for greater safety, in a dry place, protected from dust and at room temperature between 15 °C and 35 °C. Do not expose to direct sunlight.

The shelf life of sterilization is variable depending on the efficiency of the packaging and storage conditions. In closed locations it will be 2 months for surgical grade paper packaging.

**Note:** Sterile products should not be transported together with contaminated or dirty products. The conditions of the storage area may interfere with the continuity of the sterilization of the product

# 5. Cleaning agents and disinfectants

**Cleaning and sterilization step - Detergents used in Riellens' validation**

Riellens does not recommend these detergents in preference to others that are available. Other detergents may work equally well or better in conjunction with the equipment being used. The detergent manufacturer's instructions for use must be followed.

Ultrasonic Bath - A mild agent is recommended to remove all visible soil and/or debris, blood, and other contamination from the devices.

If cleaning is delayed, place devices in a bath of warm cleaning solution to prevent drying of soil and debris.

The enzymatic detergent manufacturer's instructions for use must be followed.
The suitability of alternative detergents should be verified by referring to the detergent manufacturer's instructions for use and/or physical testing.

**Enzymatic Detergent**

Made from enzymes that act specifically on organic matter, such as blood, feces, mucus, organic fluids, etc., degrading and dissolving it in a short time. It is enough to immerse the products in the enzymatic solution for a few minutes for total degradation of the organic matter, even in places that are difficult to be removed by mechanical agents, such as brushes.

The enzymatic detergent has a neutral pH, a factor that preserves products and instruments.

**Preparation Method:**

The enzymatic solution must be prepared in the following proportion: 5 ml of the enzymatic detergent for each liter of water, at room temperature, without the need for any other additive or chemical.

**Note:** Personal protection for operators must be provided according to the detergent manufacturer's instructions.

# 6. Examples for end of useful life

Digital wrench

Healer

Screw

# 7. Frequently asked questions

**Can we use other sterilization parameters?**

Conditions other than those recommended by Riellens that can also lead to safe and sterile medical devices can be used. It is the processor's responsibility to validate and maintain its processes and equipment in accordance with applicable standards. However, Riellens keeps the parameters 134 °C for 18 minutes, and its effectiveness is guaranteed.

**Can I not follow these cleaning and sterilization guidelines?**

With these cleaning and sterilization guidelines, Riellens provides a validated procedure to ensure that products are clean and sterile. According to the standard Sterilization of health care products - Information to be provided by the manufacturer for the processing of resterilizable health care products EN ISO 17664, it remains the responsibility of the processor to ensure that proper equipment, materials and personnel are used in the processing, as well as in the actual performance, to achieve the desired result. Likewise, any deviation by the processor from the instructions provided herein must be properly evaluated for effectiveness and potential adverse consequences.

**Which cement should I use to make the definitive prosthesis? And which is the ideal quantity?**

Use the zinc phosphate-based cement, always according to the quantity indicated by the manufacturer

**What can happen to the patient when too much restorative cement is used?**

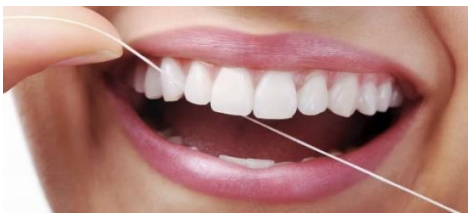
Peri-implant accumulation of bacterial plaque; therefore the use of excessive cement must be avoided.

# 8. Post-implementation care

**Proper Oral Hygiene**

**1. Use dental floss**

Roll about 50 cm between your fingers. Wrap each tooth in a "C" shape and slide from top to bottom from the gum margin, never against it.



**2. Brush your teeth properly**

Use short, gentle movements so you do not hurt your gums. Start from the outside, then go to the inside surface, followed by the chewing surfaces. Finish by brushing your tongue.

**3. Finish with mouthwash**

To complete hygiene, use 20ml of the mouthwash and swish in your mouth for 30 seconds, then discard it.

**Post-implementation care**

1) Avoid exposure to the sun, hot and hard food, and physical efforts at least until the return to remove the stitches.

2) Eat liquid or pasty and cold food for at least 48 hours or as directed by the dentist (milk, juice, etc.).

3) Rest and sleep with your head elevated (sit up when resting and put pillows under your head at bedtime), avoiding drooping.

4) Brush your teeth and tongue as usual, avoiding the surgery areas.

5) Rinse your mouth gently 3 times a day with a mouthwash indicated by the dentist, starting only 24 hours after surgery.

6) Make cold compresses on the external side (face) in the first 24 hours for 20 minutes and rest for 20 minutes.

7) Apply liquid Vaseline or protective creams to your lips to keep them lubricated, avoiding dryness.

8) If you have high fever, edema and difficulty opening your mouth for more than three days, persistent pain, or excessive bleeding, contact your dentist immediately.

9) Strictly follow the prescribed medication schedule.

**Advise the patient to see the dental surgeon periodically.**

# Annotations