PRATICAL GUIDE

Techniques for using, cleaning and sterilizing Riellens products including magnetic resonance imaging MRI

Welcome!

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

Certificates

Riellens is in compliance with ISO 13485 and RDC 16 Anvisa Good Manufacturing Practices of Medical Products.

Content

Purpose of this document and general information

Purpose of this document

This document provides general guidance for qualified dentists, reporting procedures for correct handling of medical devices provided by Riellens. The products guarantee the integrity and cleanliness of the product until the use of the professional. It also provides inspection guidelines to determine when an instrument has reached the end of its life and should be replaced and MRI magnetic resonance information.

General information

The applicability of these guidelines to Riellens devices is indicated on the respective labels and in the instructions for use (IFU), where applicable. For detailed explanations of 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 described methods. The guidelines are based on validated processes. It is recommended to follow these instructions to avoid negatively affecting product performance. Whenever the instructions for use of a particular product show other conditions of the procedure, they will replace the recommendations given in these general guidelines.

As regards conflicting national requirements for cleaning and sterilization, these should 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 use and correct handling of the products are under the sole responsibility of the user.

Information on Riellens components likely to contact with MRI magnetic resonance environments is intended to provide the data necessary for radiologists to provide safe diagnostics.

Note: According to the Standard for Sterilization of Health Products - Information to be provided by the manufacturer for the processing of re-sterilizable health product EN ISO 17664, it remains the responsibility of the user to ensure that possible reprocessing, such as equipment used, materials and personnel in the reprocessing may cause undesired results. Likewise, any deviation from inadequate assessment

of the professional can cause adverse consequences to the patient. Riellens RECOMMENDS SINGLE USE. BEING FORBIDDEN TO RE-STERILIZE its 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 is usually done manually or mechanically using water with detergents or enzymatic products. Complete cleaning is essential prior to disinfection and sterilization, such as inorganic and organic materials remaining in the processes described.

After cleaning, no visible contamination should be found by naked eye inspection 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 product free of viable microorganisms.

Validation

Documented procedure to obtain, record and interpret the results required to establish whether a process will be consistent in the manufacturing of health products in accordance with predetermined specifications.

Autoclave

It is a device used to sterilize products through 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 specific product can be reduced to a very low number, but never to zero. This probability can only be ensured by validated processes.

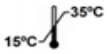
Sterility Assurance Level (SAL): probability of a single microorganism in the amount of 1,000000 in an item after sterilization. The term SAL takes a quantitative value, usually 10-6.

Abbreviations

ºC	Degrees Celsius
ºF	Degrees Fahrenheit
ASTM	American Society for Testing and Materials
EN	European Standard
IFU	Instructions for Use
MRI	Magnetic Resonance Imaging
SAL	Sterility Assurance Level (SAL): probability of a single microorganism

Explanation of symbols on the 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
	CE Organismo notificado / CE Notified Body / CE Organismo Notificado
	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
	Representante autorizado na Comunidade Européia Authorized representative in the European Community Representante autorizado em la Comunidad Europea
	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 específicas 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 específicas de uso

Magnetic Resonance Information (MRI)

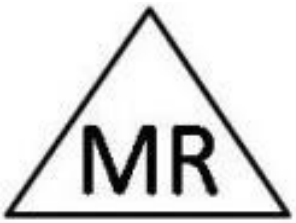
The following MR safe and MR conditional magnetic resonance definitions were developed by the American Society for Testing and Materials (ASTM) International. [1]
This section is provided to provide the MR symbol and other MR related information.

MR Safe
Items that pose no known risks in all MRI environments are labeled as MR Safe. This includes all Riellens products that are non-conductive, non-metallic and non-magnetic. For example 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.

MR Conditional
Items that have demonstrated that they 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 of 1.5-3.0 Tesla
- Magnetic field of maximum spatial gradient of 4000 Gauss / cm (40 T / m)
- Maximum reported MR system, whole body average specification (SAR) rate 4 W / kg (first level controlled mode)

Normal operation mode of MR system



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

Magnetic resonance related heating

In non-clinical worst-case tests, some metal Riellens products caused the following rise in maximum temperature for 15 minutes of magnetic resonance with 1.5 and 3.0 Tesla.
Elevated temperature poses no known hazard to the patient.

	1,5 Tesla	**3,0 Tesla**
	64 MHz	128 MHz
Maximum MR system, whole body was calculated	4 W/Kg	4 W/Kg
Measured values of calorimetry, total body mean	2,1 W/Kg	2,7 W/Kg
Highest temperature change (all tests) Magnetic field	+4,1ºC	+2,9ºC
of maximum spatial gradient	4000 W/Kg	4000 W/Kg
Test system	Magnetom (active, horizontal protected field)	Excite, HDx
	Numaris/4 Software, Syngo MR 2002B DHHS Version	Software 14X.M5
	Siemens Medical Solutions, Marvern, PA, USA	General Electric Healthcare, Milwaukee, WI, USA.

Information on artifacts

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

Pulse sequence	**T1-SE***	**T1-SE**	**GRE****	**GRE**
Flat orientation	Parallel	Perpendicular	Parallel	Perpendicular
Empty sign size ***	2754 mm2	2229 mm2	4458 mm2	5463 mm2

* T1-SE: longitudinal relaxation, spin echo sequence

** GRE (low tilt angle): gradient and echo magnetic resonance sequence

*** Maximum empty size found in all tests

Notes:

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

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

1. Use

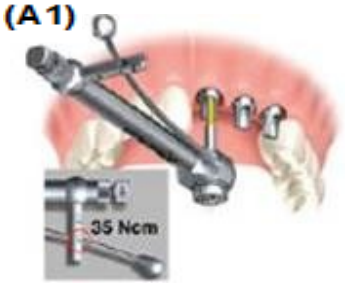
Technique for use:

The modifications of the Abutment can be carried out with abundant irrigation of water. Extraoral modification of the abutment is recommended.

Clinical procedure:

1. Select the appropriate abutment and check the occlusal clearance
2. Connect and tighten the Abutment. It is recommended to check the final abutment seat using radiographic images
3. Tighten the Abutment with the appropriate key, as shown in figures (A1) and (A2). Recommended Torques / Keys used Abutment/Mini Abutment x Key, are located in the Instruction of use of the product.

(A1)

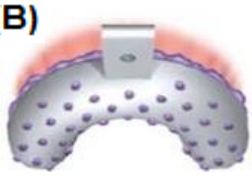


(A2)

Caution: for all types of connection never exceed the prosthetic tightening torque stated in the product use instruction. Excessive tightening of the Abutment/Mini Abutment can lead to a screw fracture.

4. Modify the Abutment, if necessary, using abundant irrigation
5. Make a standard impression, following protocol for open or closed tray.

(B)



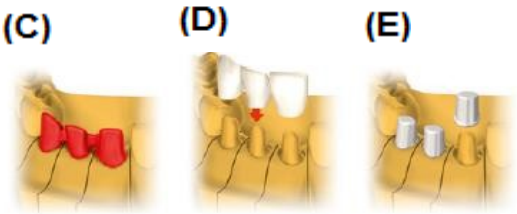
6. Reline after sealing the access hole. Make sure there is no excess cement.

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

Laboratory procedure:

7. Produce a working model with removable gingival material
8. Prepare a crown or bridge using the conventional casting technique (C + D). For aesthetic abutments, plastic copings, it can be used as casting standards (E)

(C) (D) (E)



9. Cement the crown or structure, if applicable.

Clinical procedure:

10. Remove temporary restoration, if applicable
11. Cement the final crown on the structure using conventional access hole procedures (F). Make sure there is no excess cement.

(F)

Caution: Do not temporarily cement when cementing ceramic crowns and bridges, it may increase the risk of micro-fractures.

2. Cleaning

Cleaning procedure Mechanics

Required equipment

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

Ultrasonic bath large enough to allow full 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 in the product that must be removed with the brush, the cleaning step should be repeated as above.

Manual cleaning procedure

The products must be cleaned, disinfected and sterilized before each use.

Place the pieces in the cleaning bath to remove the organic matter as soon as possible after use; remove dirt from components by hand-brushing (soft-bristled brushes); use enzymatic detergent according to the dilution instructions and exposure time determined by the manufacturer, taking into account the criteria given on page 15 of this guide and concentration as specified in the detergent manufacturer's instructions. Rinse with drinking water for removal of chemical residues and detergents. Dry the component always using soft disposable soft tissue.

Note:

The cleaning procedure is indicated for products subject to rework, that is, reusable as: Analog, transfer and keys.

Warning:

Avoid mechanical damage, do not mix heavy devices with delicate ones. Pay particular attention to cutting edges, both to avoid injury and to avoid damage to medical devices.

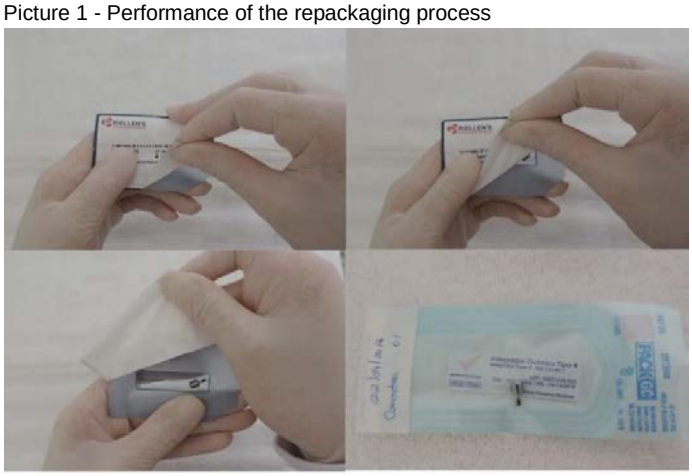
3. Sterilization

Riellens products are not sterile, so they should be sterilized by autoclaving in the sterilized material Central Office (CME) of the clinic, according to the professional protocol and manufacturer's instructions, before being used in the patient.
The sterilization process aims at the total elimination of microorganisms (viruses, bacteria, microbes and fungi). Products already packaged and properly identified must be forwarded to the Auto Clave (follow instructions for use according to the equipment manufacturer's manual).

Package

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

Picture 1 - Performance of the repackaging process



Picture 2 - Autoclavable package

Provision of products in the Autoclave

Remove the inner basket from the camera with the shelves and assemble the load outside the equipment.

Place the products to be sterilized in the chamber, do not remove the shelves (the product must have dimensions compatible with the storage capacity of the shelves). Placement in the autoclave must be performed in such a way that the steam can circulate freely and pass through the entire package. The products should be positioned so that the paper faces up.

Picture 3 - Arrangement of the products in the autoclave

Parameters for autoclaving :

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

Biological indicators

Riellens indicates the control of the efficacy of sterilization in the autoclave by performing a control test once a week or at least every 30 days. The population of resistant spores is inoculated onto a strip of paper in a thermoplastic vial which serves as the culture flask. A small breakable glass ampoule containing culture medium from the Bacillus stearothermophilus ATCC 7953 is also in the vial. Indicators should be incubated no later than 3 hours after sterilization, respecting the reaction time, ranging from 24 to 48 hours.

Correctly incubated, the medium changes its color to yellow, when viable spores exist and sterilization was ineffective. As soon as a control turns yellow, it must be properly registered and then autoclaved and discarded. The process is only effective when the medium does not change color.

Picture 4 - Biological indicator vial

Preventive maintenance of the equipment (Autoclave) Daily:

- Clean the chamber and the door seal
- Check door lock conditions

Weekly:

- In addition to the previous items;
- Replace the distilled water in the tank and clean the inside.

Monthly:

- In addition to the previous items;
- Clean and unclog filters and valves;
- Check and reconnect electrical system contacts and hydraulic connections
- Test the safety valve by pulling on its loop five times.

Semiannually:

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

Annually:

- In addition to the previous items;
- Adjust the water flow of the vacuum pump;
- Perform the calibration of the protection and control instruments;
- Validate the security and control elements;
- Adjust the door locking system;
- Check ground conditions and quality
- Perform the hydrostatic test and evaluation.

Warning: The use of non-sterile products may lead to tissue infection or infectious diseases

4. Storage / Handling

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

The shelf life of the sterilization varies depending on the efficiency of the packaging and storage conditions. In enclosed places, it will be of 2 months for surgical grade paper packaging.

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

5. Cleaning and disinfectants agents

Cleaning and sterilization step - Detergents used in Riellens validation
Riellens does not recommend such detergents in preference to others that are available. Other detergents may work equally well or better in conjunction with the equipment being used. The instructions for use of the detergent manufacturer must be followed.

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

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

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

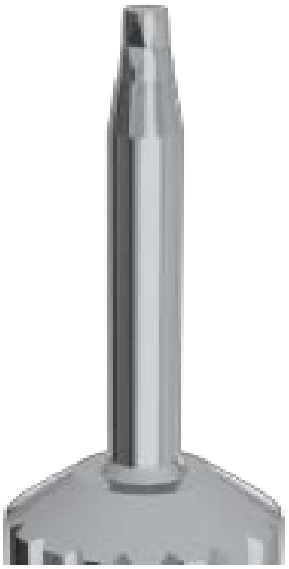
Enzyme Detergent
Made from enzymes that act specifically on organic matter, such as blood, feces, mucus, organic fluids, etc., degrading and dissolving it in a short time. It is enough that the products are immersed in the enzymatic solution for a few minutes for total degradation of the organic matter, even in places of difficult access for removal by mechanical agents, like brushes.
The enzymatic detergent has neutral pH, product preservation factor and instrumentation.

How to prepare:
The enzymatic solution should 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 additives or chemicals.

Note: Personal protection for operators should be provided according to the instructions of the detergent manufacturer.

6. Examples for end of life

Digital key



Healer

Screw

7. Frequently asked questions

Can we use other sterilization parameters?

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

Can I not follow these cleaning and sterilization guidelines?

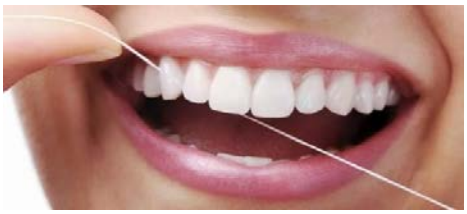
With these cleaning and sterilization guidelines, Riellens provides a validated procedure to ensure that the products are clean and sterile. According to the Standard for Sterilization of Health Products - Information to be provided by the manufacturer for the processing of re-sterilizable health product EN ISO 17664, it remains the responsibility of the processor to ensure that in processing, as effectively as performing, materials and personnel are used in order 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.

8. Post-installation care

Adequate Oral Hygiene

1. Use dental floss

Wrap about 50 cm between your fingers. Wrap each tooth into a "C" and slide it up and down from the edge of the gum, never against it.



2. Brush teeth properly

Use short, gentle strokes so as not to hurt the gums. Start from the outside, then the inner surface, followed by the masticatory surfaces. Complete brushing your tongue.

3. Finish with mouthwash

To complete the hygiene, rinse 20 ml of mouthwash for 30 seconds and discard.

Post-installation care

1) Avoid sun exposure, hot and hard foods, and physical exertion at least until the return for stitch removal.
2) Liquid or pasty and cold diet (food) for at least 48 hours or as directed by the dentist (milk, juice, etc.).
3) Rest and sleep with the head higher (sit when resting and put pillows under your head at bedtime), avoiding lowering.
4) Normal brushing of the teeth and tongue, avoiding the areas of the surgery.
5) Mild and passive mouthwash 3 times a day with oral antiseptic indicated by the dentist, starting only 24 hours after surgery.
6) Make ice packs on the outside (face) in the first 24 hours for 20 minutes and rest 20 minutes.
7) Put on liquid vaseline or protective creams on the 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 exaggerated bleeding, contact your dentist immediately.
9) Strictly follow the schedule of prescribed medication.

Advise the patient to visit the dental surgeon periodically.

Annotations