# Matrix retainer: Reprocessing Guidelines

The purpose of this document is to provide detailed instructions to guarantee the correct management of matrix retainer, a set of guidelines commonly referred to as reprocessing.

Reprocessing procedures have two main objectives:

1) patient and operator safety;

2) instrument integrity for effective reuse.

Reprocessing in fact involves chemical, thermal and mechanical stress necessary to guarantee that instruments can be safely reused but also capable of altering instruments effectiveness.

Reprocessing applies to matrix holder designed to be reused over time on many different patients.

The involved operations are subject to international guidelines for sterilization and to manufacturer's instructions for use regarding material, shape and application.
For this reason matrix retainer must be cleaned and sterilized before every use, including the first one.

Different factors contributes to reprocessing effectiveness including operator's proficiency, equipment quality and maintenance, chemical products, physical environment and procedures compliance.
Involved operators must guarantee that all the necessary reprocessing steps are correctly and safely implemented.
International or country regulations conflicting with this document, have priority recommends to follow them.

**PRELIMINAR NOTES**

**Staff training**

Everyone involved with reprocessing procedures must be trained and qualified beforehand. Training must include cleaning, disinfection, sterilization, and infection prevention & control procedures.

**Safe area**

Reprocessing protocol demands for a dedicated space separate from patient treatment areas and from non-medical staff. Size of the area depends on the type of dental practice, but its characteristics general are:

- Large enough to run operations;
- Separation between operations and storage;
- Dedicated hand-washing area;
- Surfaces, walls and floors easy to clean and disinfect;
- Room controls (e.g. temperature, humidity, ventilation, etc.);
- Limited personnel access.

**Equipment and chemicals**

The practice should be equipped with instruments and chemicals necessary for the operations of cleaning, disinfection and sterilization of instruments, all compliant with international regulations and well maintained in accordance with manufacturer's instructions.

**RECOMMENDATIONS**

For correct instrument handling

- For the correct sterilization operations must be carried out from the first use, as soon as the reusable instrument is removed from the packaging.
- Used/contaminated instruments must be moved from use area to reprocessing area with appropriate containers in order to avoid any contacts with the operator and with the environment.
- Used / contaminated instruments must not be rinsed before decontamination or disinfection to avoid contamination of the operator or work area.
- A very accurate rinsing must be performed after any steps where the instrument has been exposed to chemical

agents for cleaning and disinfecting purposes in order to remove residuals

**WORKFLOW:**

| | |
|---|---|
| 1 | **DECONTAMINATION** |
| 2 | **CLEANING** |
| | 2.1.a. **Automatic** cleaning<br>2.1.b. **Manual** cleaning<br>2.1.c. **Manual Ultrasonic** cleaning |
| | 2.2. **Disinfection** (for 2.1.b and 2.1.c) **e Drying** (per 2.1.a and 2.1.b) |
| 3 | **INSPECTION** |
| | 3.1. **Visual Check** |
| | 3.2. **Manitenance** |
| 4 | **PACKAGING** |
| | 4.1. **Packaging** |
| | 4.2. **Traceability** |
| 5 | **STERILIZATION** |
| 6 | **STORAGE** |

| **1. DECONTAMINATION** | |
|---|---|
| ***Equipment required*** | Purified or sterile water: max 100 CFU/ml e 0.5 EU/ml. Residues of hard water or water with higher contamination (microorganism and endotoxins) can cause staining of the instruments or prevent effective decontamination.<br>Disinfectant intended for manual disinfection, applied in according to the manufacturer's guidelines concerning time and concentrations.<br>Plastic cassette and decontamination bath. |
| ***Procedure*** | 1. Immediately after proceed, removing gross organic and material residuals using soft disposable wipes and immerse instruments in a decontamination bath with a cleaning/decontaminating agent to avoid solidification of composites, cements and glass ionomers.<br>2. Instruments should be immersed in the decontamination bath using a sterilization cassette, depending on availability and type of instruments. |
| ***Notes*** | The guidelines provided by the cleaning/decontaminating agent manufacturer regarding concentrations and time should be strictly followed. |

| **2.1.a. CLEANING - Automatic cleaning** | |
|---|---|
| ***Equipment required*** | Thermal disinfector<br>Tray: Most thermal disinfectors allow inserting also trays inside; in any case, their use is not mandatory.<br>Cleaning agents: depending on the material of the instrument, follow the manufacturer's guidelines concerning time and concentrations; avoid cleaning agents with high pH (>8.5). |
| ***Procedure*** | 1. Initially manually rinse the instruments before placing them inside the thermal disinfector, opening and closing the instruments or moving the cursor under abundant running water, alternating brushing strokes in the hinge area (using a non-metallic brush with jets of compressed air) and checking that all residues in the hinged areas and in the cursor sliding area have been removed.<br>2. Load the instruments using the modalities and precautions described in the instructions that come |

with the thermal disinfector, and follow these for what concerns both loose instruments and those inside the cassettes.

N.B. Some thermal disinfectors also use ultrasound during their cycle; in this case, do not load instruments that may be damaged by the ultrasounds unless specifically mentioned in the manufacturer's guidelines of the thermal disinfector under their own responsibility. Place the instruments in the cassette making sure that they do not come into contact to avoid damages during the procedure and ensure proper washing;

3. If the thermal disinfector used does not feature automatic drying of the instruments, dry them at the end of the cycle using compressed air or disposable lint-free wipes.

N.B. The presence of humidity residues on the instruments may compromise the outcome of the final sterilization and favor the presence of spots once the sterilization procedure is finished.

***Notes*** Make sure that the thermal disinfector has proven efficacy (ex. CE mark), that it has been properly installed and it has received maintenance procedure and periodic tests.

**2.1.b. CLEANING - Manual cleaning**

***Equipment required*** Purified or sterile water: max 100 CFU/ml e 0.5 EU/ml, and the use of a syringe to ensure that the cleaning solution reaches all parts.

Cleaning agents: depending on the material of the instrument, follow the manufacturer's guidelines concerning time and concentrations; avoid cleaning agents with high pH (>8.5).

***Procedure***

1. Rinse the instruments manually by opening and closing them or moving the cursor under abundant running water, alternating brushing strokes in the hinge area using a non-metallic brush, with jets of compressed air and checking that all residues in the hinged areas and in the cursor sliding area have been removed.
2. Completely immerse the instrument or its parts.
3. Keep the instrument in the solution for at least the time specified by the detergent manufacturer's instructions.
4. Remove the instrument or its parts from the cleaning liquid and rinse it thoroughly with purified or sterile water until the detergent is completely removed;
5. Inspect instrument and, if necessary, repeat the procedure from the beginning.

***Notes*** WARNING: automatic cleaning is always to be preferred to manual cleaning, even in case of manual cleaning with an ultrasonic device. Manual cleaning should be used only when the instrument properties are not compatible with automatic cleaning device. Never use metal brushes or other tools that may damage the instrument.

**2.1.c. CLEANING - Manual ultrasonic cleaning**

***Equipment required*** Cleaning agent: choose the detergent depending on the instrument material and follow manufacturer's guidelines concerning time and concentration of the cleaning agent.

Ultrasonic bath must be large enough to allow complete immersion of the instrument and work in a 25 - 50 kHz frequency range, without exceeding temperatures stated by the detergent manufacturer's instructions.

***Procedure***

1. Before proceeding with cleaning, manually rinse the instrument with abundant running water.
2. Prepare the bath and completely immerse the instrument and all its parts.
3. Activate the bath for minimum of 15 minutes or the time recommended by the detergent's manufacturer.
4. Remove the instrument or its parts from the detergent and rinse abundantly with purified or sterile water and ensure that all traces of detergent solution are removed.

5. Inspect the instrument, and, if necessary, repeat the cleaning procedure from the beginning.

***Notes*** WARNING: automatic cleaning is always to be preferred to manual cleaning, even in case of manual cleaning with an ultrasonic device. Manual cleaning should be used only when the instrument properties are not compatible with the automatic cleaning device.

Never use metal brushes or other tools that may damage the instruments.

**2.2. CLEANING - Disinfection (for 2.1.b and 2.1.c) and Drying for manual cleaning (2.1a. and 2.1.b)**

***Equipment required*** Purified or sterile water: max 100 CFU/ml e 0.5 EU/ml, and the use of a syringe in case of instruments with hollow parts to ensure that the leaning solution reaches all parts.

Disinfectant intended for manual disinfection, applied in according to the manufacturer's guidelines concerning time and concentrations. A filtered, compressed air device or clean lint-free wipes are valid options for the drying.

Bath: large enough to allow complete immersion of the instrument.

***Procedure***

1. Prepare a bath large enough to accommodate the instrument.
2. Keep the instrument in the solution for at least the time specified by the disinfectant manufacturer's instructions.
3. Rinse the instrument at least 1 minute in running water until and ensure that all traces of disinfectant solution are removed.
4. Dry using filtered, compressed air device or clean, lint-free wipes;
5. Inspect instrument, especially in the cavities and, if necessary, repeat the cleaning procedure from the beginning.

**3. INSPECTION**

**3.1. Visual check**

***Equipment required*** Magnifying device and optimal lighting.

***Procedure***

1. Visually inspect all the instruments for the presence of any residues;
2. Carefully check cavities, hinges and joints.
3. In case impurities and residues are detected, repeat the cleaning procedure.
4. In case of corrosion, alteration, wear or any other modifications that may compromise or limit instrument functionality, it is mandatory to proceed with maintenance procedures.

***Notes*** All instruments should be inspected before proceeding with sterilization.

**3.2. Maintenance**

***Equipment required*** Magnifying tool and proper lighting conditions. Anticorrosion oil and lubricating oil for stainless steel.

***Procedure***

1. Visually inspect instruments to identify parts showing evidence of corrosion, wear, alteration or other defects that may alter instrument functionality
2. In case of corrosion apply a small quantity of anticorrosion oil;
3. Always check the effectiveness of the maintenance intervention and if necessary (negative or non acceptable results) proceed with instrument scrapping and replacement.
4. After any of the above action, repeat cleaning/disinfecting procedures to remove residuals of maintenance.

***Notes*** Maintenance operations are strongly recommended as they have serious consequences on operators and

patient safety.

## 4. PACKAGING

### 4.1. Packaging

***Equipment required***

Pouches or crepe paper certified for medical use and steam sterilization, in order to ensure steam permeability, thermal and mechanical protection throughout the sterilization process.

A suitable cassette according to instruments size.

***Procedure***

To sterilize a single instrument, place it inside the envelope and seal it.

If using crepe paper, use 2 sheets of paper to wrap each cassette.

***Notes***

Wrapping paper and wrapping techniques must comply with the most common standards (AAMI ST79, ISO 11607, CE mark, FDA).

### 4.2. Traceability

***Equipment required***

Chemical/biological process indicators: placed so as to be visible from the outside, of the type described in ISO11138-3 and ISO11140.

Labels for process indications.

***Procedure***

1. Depending on type, insert or apply the chemical indicator.
2. Visibly apply the label on each cassette with the at least the following information:
   - Autoclave identifier/number of device
   - Packaging and sterilization date
   - Signature or operator identifier
   - Expiration date
   - Sterilization sequential number.

***Notes***

Six different chemical indicator types are available:

- Type 1: only indicate if they have been exposed to sterilization process
- Type 2: are for use in specific test procedures (e.g. Bowie-Dick test for air removal)
- Type 3: show evidence of exposure to a predetermined sterilization process variable (e.g. 134°C)
- Type 4: are intended to indicate exposure to 2 or more process variables (e.g. time and temperature)
- Type 5: react to all sterilization variables
- Type 6: are intended to match critical variables of specified sterilization cycles.

## 5. STERILIZATION

***Equipment required***

The matrix retainers can be sterilized using all the sterilization techniques approved by international standards, following the instructions provided by the manufacturer of the devices employed based on the technique used and following instructions in terms of temperatures and maximum attainable sterilization cycles.

If sterilizing trough autoclave we suggest class B steam sterilizer:dimensions and features compatible with dental studio requirements, equipped with vacuum pump to remove air from the chamber and ensure sterilization of porous materials, wrapped items and instruments with cavities. The device must be compliant with the current regulations applicable to autoclaves intended for the sterilization of porous materials, wrapped objects and hollow bodies. The same regulations describe also maintenance procedures and sterilization protocols regarding time and temperature.

***Procedure***

1. Place wrapped cassettes or envelopes in the sterilizer.
2. Select the sterilization program according to the protocols described below making sure to select the pre-

vacuum option and wait for the entire program duration:

| Method *(EU)* | *Moist heat sterilization according to ISO 17665* |
|---|---|
| Cycle | Pre-vacuum (dynamic air removal) |
| Temperature | 134° C - 137° C (273° - 279° F) |
| Duration * | 3 minutes |
| Drying time ** | 30 minutes (in chamber) |

| Method *(US)* | *Moist heat sterilization according to ANSI/AAMI ST79* |
|---|---|
| Cycle | Pre-vacuum (dynamic air removal) |
| Temperature | 132° C (270° F) |
| Duration * | 4 minutes |
| Drying time ** | 30 minutes (in chamber) |

* Period for which the load and entire chamber is maintained at the sterilization temperature
** Period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases

Maximum attainable temperature 180°C.
Max number of cycles: 3000.

***Notes***

Do not use flash, radiation or chemical sterilization with substances like formaldehyde and ethylenoxide.

Longer exposure time and higher temperature can be used with a potentially negative impact on instrument lifetime. We strongly recommend the use of purified or deionized water.

## 5. STORAGE

***Equipment required***

After sterilization, reusable instruments should be stored in the sterilization wrap or rigid container in a dry and dust-free place.
The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions, and handling.

***Procedure***

1. Store sterilized material in the dedicated storage area.
2. Ensure the necessary separation between sterile and non-sterile packages.
3. Make sure that storage area meets humidity, temperature and hygienic storage conditions.
4. Follow the protocol that implements a sterile barrier between the storage area and other areas.
5. Always check labels, indicators and packaging integrity before using stored instruments.

***Notes***

It is advisable to implement a strict conservation protocol in accordance with the guidelines of the EP (European Pharmacopoeia), and JP (Japanese Pharmacopoeia).

We recommend keeping sterile material separate from non-sterile material.

Sterile conditions are guaranteed only when the certified medical wrapping paper is used and the packaging is preserved unopened and undamaged.