

The purpose of this document is to provide detailed instructions to guarantee the correct management of ROCKMED reusable instruments, a set of guidelines commonly referred to as reprocessing. Reprocessing procedures have two main objectives: 1) patient and operator safety and 2) instrument integrity for effective reuse. Reprocessing in fact involves chemical, thermal and mechanical stress all necessary to guarantee that instruments can be safely reused but also capable of altering instruments effectiveness.

Reprocessing applies to all non-disposable medical instruments 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 all ROCKMED Dental instruments must be cleaned and sterilized before every use, including the first one.

Different factors contribute 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 and ROCKMED recommends to follow them.

PRELIMINARY 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 are general:

- 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 (i.e. temperature, humidity, ventilation, etc.)
- Limited personnel access

Equipment and chemicals

The practice should be equipped with instruments and chemicals necessary for cleaning, disinfection, all compliant with international regulations and well maintained.

RECOMMENDATIONS

For correct instrument handling:

- Following the previous operation, if applicable, proceed with instrument sterilization before use
- 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
- We strongly recommend to always apply a preliminary disinfection/decontamination to prevent operator and environment contamination that may happen during cleaning, especially when washing instruments under running water
- 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

WORK FLOW

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2. CLEANING

2.1a AUTOMATIC CLEANING

2.1b MANUAL CLEANING

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2.2 DISINFECTING AND DRYING (2.1a / 2.1b)

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3.2 MAINTENANCE

4. PACKAGING

4.1 PACKAGING

4.2 TRACEABILITY

5. STERILIZATION

6. STORAGE

1. DECONTAMINATION

Equipment required

Purified or sterile water: max 100CFU/ml and 0.5EU/ml, as residues of hard water or water with higher contamination (microorganism and endotoxins) can cause staining of the instruments or prevent effective decontamination.

Disinfectant intended for manual disinfection, applied according to the manufacturer's guidelines concerning time and concentrations.

Plastic cassette and decontamination bath.

Procedure

Important: refer to the Appendices that follow any specific procedures in relation to the characteristics of the different types of instruments.

1. The instruments must be immersed as soon as possible after use in order to prevent coagulations and incrustations of the blood or the serum or other contaminating substances. The instruments that have come into contact with materials prone to hardening (glass ionomers, cement, etc.), must be delicately cleaned using a paper towel before immersing them in the decontamination bath and before such materials have time to harden.
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. CLEANING

2.1a AUTOMATIC CLEANING

Equipment required

Thermal disinfectant.

Trays: Most thermal disinfectors allow inserting also trays inside; in any case, their use is not mandatory.

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

Important: refer to the Appendices that follow any specific procedures in relation to the characteristics of the different types of instruments.

1. Load the instruments using the modalities and precautions described in the instructions that come with the thermal disinfectant, 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 disinfectant under their own responsibility.

2. If the thermal disinfectant 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 disinfectant has proven efficacy (EC marking or FDA approval in accordance with ISO15883), that it has been properly installed and that it has received maintenance procedures and periodic tests.

2.1b MANUAL CLEANING

Equipment required

Purified or sterile water: max 100 CFU/ml and 0.5 EU/ml and syringes (up to 50ml) in case of instruments with hollow parts and cannulation 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

Important: refer to the Appendices that follow any specific procedures in relation to the characteristics of the different types of instruments.

1. Before proceeding with cleaning, manually rinse the instrument with abundant running water.
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 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.

ROCKMED instruments with blind holes in a diameter smaller than 3mm come with a cleaning piston that helps free holes from impurities, to be used together with water and air, through the above-mentioned procedure.

2.1c MANUAL ULTRASONIC CLEANING

Equipment required

Cleaning agent: choose the detergent depending on the instrument material and follow the manufacturer's guidelines concerning time and concentrations 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

Important: refer to the Appendices that follow any specific procedures in relation to the characteristics of the different types of instruments.

1. Before proceeding with cleaning, manually rinse the instrument with abundant running water.
2. Completely immerse the instrument or 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.

ROCKMED instruments with blind holes in a diameter smaller than 3mm come with a cleaning piston that helps free holes from impurities, to be used together with water and air, through the above-mentioned procedure.

2.2 DISINFECTION AND DRYING FOR MANUAL CLEANING (2.1a / 2.1b)

Equipment required

Purified or sterile water: max 100 CFU/ml and 0.5 EU/ml and syringes (up to 50ml) in case of instruments with hollow parts and cannulation to ensure that the cleaning solution reaches all parts.

Disinfectant intended for manual disinfection, applied 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

Important: refer to the Appendices that follow any specific procedures in relation to the characteristics of the different types of instruments.

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 the instrument, especially in case of blind holes, cavities and cannulations and, if necessary, repeat the cleaning procedure from the beginning.

3. INSPECTION

3.1 VISUAL CHECK

Equipment required

Magnifying device and optimal lighting.

Procedure

Important: refer to the Appendices that follow any specific procedures in relation to the characteristics of the different types of instruments.

1. Visually inspect all the instruments for the presence of any residues.
2. In case impurities and residues are detected, repeat the cleaning procedures.
3. 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

Important: refer to the Appendices that follow any specific procedures in relation to the characteristics of the different types of instruments.

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 actions, 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.

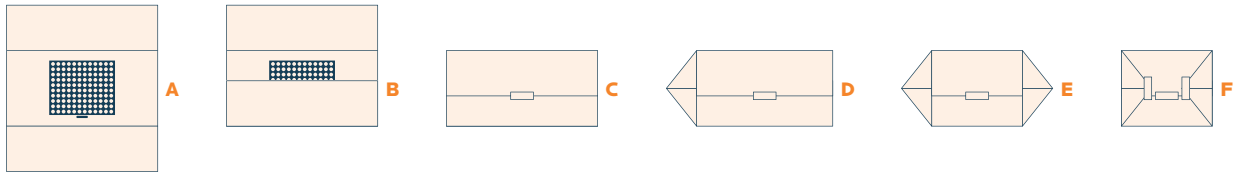
Procedure

Important: refer to the Appendices that follow any specific procedures in relation to the characteristics of the different types of instruments.

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.

Envelope wrapping method example:



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 externally, of the type described in ISO11138-3 and in ISO11140.

Labels for process indications.

Procedure

1. Depending on type, insert or apply the chemical/biological indicator
2. Visibly apply the label on each cassette with the at least the following information:
 - Autoclave identifier/number
 - 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 (i.e. Bowie-Dick test for air removal)
- Type 3 show evidence of exposure to a predetermined sterilization process variable (i.e. $134^{\circ}\text{C} \pm 3^{\circ}$)
- Type 4 are intended to indicate exposure to 2 or more process variables (i.e. 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

ROCKMED instruments 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 ROCKMED's instructions in terms of temperatures and maximum attainable sterilization cycles.

If sterilizing through autoclave ROCKMED suggests 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 following regulations: EN285, EN13060, EN ISO17665 and ANSI/AAMI ST79. The same regulations describe also maintenance procedures and sterilization protocols regarding time and temperature.

Procedure

Important: refer to the Appendices that follow any specific procedures in relation to the characteristics of the different types of instruments.

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 entire program duration:

Method (US)	Moist heat sterilization according to ANSI / AAMI ST79	Method (EU)	Moist heat sterilization according to ISO 17665
Cycle	Pre-vacuum (dynamic air removal)	Cycle	Pre-vacuum (dynamic air removal)
Temperature	132°C (270°F)	Temperature	134° - 137°C (273° - 279°F)
Duration ⁽¹⁾	4 minutes	Duration ⁽¹⁾	3 minutes
Drying time ⁽²⁾	30 minutes (in chamber)	Drying time ⁽²⁾	30 minutes (in chamber)

⁽¹⁾ Period for which the load and entire chamber is maintained at the sterilization temperature

⁽²⁾ 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. The drying time varies due to load configuration, wrapping method, and material

Notes

Do not use flash, radiation, plasma 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. We strongly recommend the use of purified or deionized water. Important: Some instruments or their parts are manufactured using plastic and/or thermo-sensitive materials. Strictly follow the instructions provided by ROCKMED – also reported in the Appendices that follow – featuring the maximum attainable temperatures and the maximum number of sterilization cycles. **ROCKMED** will not answer for damage to instruments caused by failure to observe such instructions.

6. 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

ROCKMED recommends storage conditions in accordance with international guidelines: EP (European Pharmacopoeia), USP (United States 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.

APPENDICES

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Appendix A

Stainless steel instruments with hinges that entail lubricating

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Extracting forceps for adults	3000
Extracting forceps for children	1500
Needle holders	2000
Tongue forceps	3000
Mouth gags	3000
Scalpel blades remover	3000
Hinged retractors	3000
Bone rongeurs	3000
Clamp-forceps	3000
Punch forceps	3000
Pliers for crowns	3000
Copper rings pliers	3000
Cutters	3000
Wire forming pliers and universal pliers	3000
Separating pliers for elastics	3000

SPECIAL PROCEDURES

Maintenance

Immediately after the drying process and the visual check, open the instrument all the way and place a few drops of lubricant 8002 or 8010 ROCKMED inside the hinge.

The amount of lubricant varies according to instrument size, but it has to be applied so as not to drip excessively.

After having applied the lubricant, open and close the instrument about twenty times.

After the above procedure, any excess oil must be removed using a clean cloth.

Appendix B

Stainless steel hinged instruments or with mobile parts or cursors that do not require lubricating

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Scissors	2000
Crown scissors	2000
Pliers for removing broken broaches	3000
Extracting forceps for silver cones	3000
Bone mills	3000
Hemostatic forceps	3000
Towel clamps	3000
Dressing forceps	3000
Orientable blade scalpel handles	3000
Crown removers	3000
Matrix retainers	3000
Calipers	3000
Thickness gauges	3000
Endo guns	1000
Bone injectors	3000
Bone scraper	3000
Retractors	3000

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, initially manually rinse the instruments before placing them inside the thermal disinfectant, 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.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

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. Then, continue with regular manual cleaning.

Appendix C

Stainless steel instruments with through-holes

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Surgical saliva ejectors	2000
Trephine graduated burs	2000
Perforated impression trays	3000
Clamps	1000
Stainless steel instrument cassettes	3000
Stainless steel instrument trays	3000
Vision punching template	3000

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, manually rinse the instruments with abundant running water before placing them inside the thermal disinfecter, letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air. Repeat the procedure until the water that flows out of the instrument is perfectly free of residues.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

If performed completely manually, rinse the instruments manually, letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air. Repeat the procedure until the water that flows out of the instrument is perfectly free of residues.

Then, continue with regular manual cleaning.

ROCKMED instruments with through-holes in a diameter smaller than 3mm come with a cleaning piston that helps free the holes from impurities, to be used together with water and air, through the above-mentioned procedure.

Manual cleaning

Use a syringe (up to 50ml) and tilt the part so that the detergent passes through the cavity.

At the end of the cleaning procedure, inspect the instrument, the cavity above all, and, if necessary repeat the cleaning procedure from the beginning.

Appendix D

Stainless steel instruments with blind holes

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Handles for mouth mirrors	3000
Mucotomes	3000
Bone curettes	3000
Bone injectors	3000
Silicone bur holders	3000
Syndesmotomes handles	3000
Scalpel handles	3000
Pliers	3000
Bone files and files in general	2000
Osteotomes	3000
Bone well	3000
Amalgam well	3000
Bone curette	3000
Guillotine forceps	3000
Non-perforated impression trays with rim	3000
Scalpel handle for microblades	3000

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, manually rinse the instruments with abundant running water before placing them inside the thermal disinfectant. Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the operation with a flow of compressed air and checking that the hole is perfectly clean.

If the blind hole is not completely clean, repeat the procedure until it is totally free of residues.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

Manually rinse the instruments with abundant running water. Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the operation with a flow of compressed air and checking that the hole is perfectly clean.

If the blind hole is not completely clean, repeat the procedure until it is totally free of residues.

Then, continue with regular manual cleaning.

Manual cleaning

Use a syringe (up to 50ml) and tilt the part so that the detergent passes through the cavity.

At the end of the cleaning procedure, inspect the instrument, the cavity above all, and, if necessary repeat the cleaning procedure from the beginning.

Appendix E

Bimetallic stainless steel instruments coated on the surface – or on part of the surface – with filler metals

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Heidemann separating spatulas with tips coated in titanium nitride	3000
Filling instruments with tips coated in titanium nitride	3000
Plastic filling instruments with tips coated in titanium nitride	3000

SPECIAL PROCEDURES

Decontamination

During the decontamination phase, do not use saline solutions and do not insert the instruments together with others built using base metals. In a saline solution, the presence of instruments coated in noble metals together with others manufactured using base metals would create a galvanic bath with serious, irreversible damages to the noble coating.

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Appendix F

Stainless steel instruments

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Probes	3000
Spreaders	3000
Pluggers	3000
Retractors	3000
Antrum probes	3000
Root elevators and root-tip picks	3000
Syndesmotomes	3000
Periotomes	3000
Excisers	3000
Gouges	3000
Sinus lift instruments	3000
Osteotomes chisels	3000
Periosteal elevators	3000
Bone applicator	3000
Dam frames	3000
Excavators	3000
Cavity preparation instruments	3000
Composite instruments	3000
Filling instruments	3000
Carvers	3000
Band pushers	3000
Band instruments	3000
Elastic instruments	3000
Stainless steel punching template	3000
Crown spreaders	3000
Periodontal pocket Probes	3000
Gingivectomy instruments	3000
Root-canal instruments	3000
Tongue depressors	3000
Bone compactors	3000
Cement spatulas	3000

SPECIAL PROCEDURES

None.

Appendix G

Stainless steel instruments with Magic Color handle (nylon and aluminum)

Maximum attainable temperature 137°C ± 3°.

Products	Max number of cycles
Probes	200
Spreaders	200
Excavators	200
Composite instruments	200
Filling instruments	200

SPECIAL PROCEDURES

Cleaning

Apply automatic or manual cleaning exclusively. Do not brush or apply ultrasonic cleaning.

During the drying phase, aim a long jet of compressed air between the metallic part and the plastic part of the instrument in order to prevent stagnant humidity that could cause deterioration both on the metallic and on the plastic part.

Sterilization

Do not exceed 137°C ± 3°.

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Appendix H

Composite instruments that can be disassembled, to disassemble during reprocessing

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Surgical mallets	3000

SPECIAL PROCEDURES

Decontamination

After use on the patient, disassemble the instrument and immerse all its parts inside the decontamination bath.

Packaging

Reassemble the instrument immediately before placing it inside the bag.

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Appendix I

Modular composite instruments, comprised of two materials

Maximum attainable temperature 137°C ± 3°.

Products	Max number of cycles
Stainless steel codicolor impression trays	2000

SPECIAL PROCEDURES

Sterilization

Do not exceed 137°C ± 3°.

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Appendix J

Stainless steel instruments that can be re-sharpened

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Curettes	300
Scalers	300

SPECIAL PROCEDURES

Maintenance

After drying, sharpen the working tip of the instrument using grinding stones or grinding cards.

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Appendix K

Stainless steel instruments that can be re-sharpened, with Magic Color handle (nylon and aluminum)

Maximum attainable temperature $137^{\circ}\text{C} \pm 3^{\circ}$.

Products	Max number of cycles
Curettes	200
Scalers	200

SPECIAL PROCEDURES

Cleaning

Apply automatic or manual cleaning exclusively.

Disinfecting and drying

During the drying phase, aim a long jet of compressed air between the metallic part and the plastic part of the instrument in order to prevent stagnant humidity that could cause deterioration both on the metallic and on the plastic part.

Maintenance

After drying, sharpen the working tip of the instrument using grinding stones or grinding cards.

Sterilization

Do not exceed $137^{\circ}\text{C} \pm 3^{\circ}$.

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Appendix L

Heat-sterilizable plastic instruments

Maximum attainable temperature 137°C ± 3°.

Products	Max number of cycles
Polycarbonate impression trays	2000
Plastic endo guns	200
Plastic surgical saliva ejectors	100

SPECIAL PROCEDURES

Automatic cleaning

During the rinse phase: if performed through thermal disinfectant, manually rinse the instruments with abundant running water before placing them in the washer, letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air. Repeat the procedure until the water that flows out of the instrument is perfectly free of residues. Then, place the instruments in the washer.

Manual cleaning

If performed completely manually, rinse the instruments manually, letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air. Repeat the procedure until the water that flows out of the instrument is perfectly free of residues. Then, continue with regular manual cleaning.

Sterilization

Do not exceed 137°C ± 3°.

Appendix M

Syringes

Maximum attainable temperature 137°C ± 3°.

Products	Max number of cycles
Syringes	500

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, manually rinse the instruments with abundant running water before placing them inside the thermal disinfecter. Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the operation with a flow of compressed air and checking that the hole is perfectly clean.

If the blind hole is not completely clean, repeat the procedure until it is totally free of residues.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

Manually rinse the instruments with abundant running water. Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the operation with a flow of compressed air and checking that the hole is perfectly clean.

If the blind hole is not completely clean, repeat the procedure until it is totally free of residues.

Then, proceed with regular manual cleaning.

Sterilization

Do not exceed max temperature of 137°C ± 3°.

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Appendix N

Aluminum instruments and colored anodized aluminum instruments

Maximum attainable temperature 160°C.

Products	Max number of cycles
Felt composite instruments	350

SPECIAL PROCEDURES

Cleaning

Apply automatic or manual cleaning exclusively.
Never use brushes or ultrasonic cleaning.

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Appendix O

Stainless steel instruments with both through-holes and blind holes

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Surgical suture forceps	3000
Perforated impression trays with rim	3000

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, manually rinse the instruments with abundant running water before placing them inside the thermal disinfectant, letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air.

Repeat the procedure until the water that flows out of the instrument is perfectly free of residues.

Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the procedure with a flow of compressed air and checking that the hole is perfectly clean.

If the blind hole is not completely clean, repeat the procedure until it is totally free of residues.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

Manually rinse the instruments by letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air. Repeat the procedure until the water that flows out of the instrument is perfectly free of residues. Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the procedure with a flow of compressed air and checking that the hole is perfectly clean.

If the blind hole is not completely clean, repeat the procedure until it is totally free of residues.

Then, proceed with regular manual cleaning.

Appendix P

Aluminum instruments with blind holes

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Aluminum burs holders	3000
Aluminum color-coded instrument trays	3000
Aluminum color-coded mouth mirror handles	3000

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, manually rinse the instruments with abundant running water before placing them inside the thermal disinfectant.

Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the procedure with a flow of compressed air and checking that the hole is perfectly clean.

If the blind hole is not completely clean, repeat the procedure until it is totally free of residues.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

Manually rinse the instruments with abundant running water. Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the procedure with a flow of compressed air and checking that the hole is perfectly clean.

If the blind hole is not completely clean, repeat the procedure until it is totally free of residues.

Then, proceed with regular manual cleaning.

Do not perform ultrasonic cleaning.

Appendix Q

Stainless steel instruments with blind holes and Magic Color handle (nylon and aluminum)

Maximum attainable temperature 137°C ± 3°.

Products	Max number of cycles
Mouth mirror handles	200
Bone curettes	200

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, manually rinse the instruments with abundant running water before placing them inside the thermal disinfecter. Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the procedure with a flow of compressed air and checking that the hole is perfectly clean. If the blind hole is not completely clean, repeat the procedure until it is totally free of residues. Then, place the instruments in the washer.

Decontamination (through manual cleaning)

Manually rinse the instruments with abundant running water. Using a non-metallic brush, thoroughly clean all the blind holes present on the instrument, completing the procedure with a flow of compressed air and checking that the hole is perfectly clean.

If the blind hole is not completely clean, repeat the procedure until it is totally free of residues.

Then, proceed with regular manual cleaning.

During the drying phase, aim a long jet of compressed air between the metallic part and the plastic part of the instrument in order to prevent stagnant humidity that could cause deterioration both on the metallic and on the plastic part.

Cleaning

Apply automatic or manual cleaning procedures exclusively.

Never use brushes or ultrasonic cleaning.

Sterilization

Do not exceed max temperature of 137°C ± 3°.

Appendix R

Perforated aluminum impression trays and color-coded impression trays in anodized aluminum

Maximum attainable temperature 160°C.

Products	Max number of cycles
Perforated aluminum impression trays	1000
Color-coded impression trays in anodized aluminum	350

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, manually rinse the instruments with abundant running water before placing them inside the thermal disinfectant, letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air.

Repeat the procedure until the water that flows out of the instrument is perfectly free of residues.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

Manually rinse the instruments by letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air.

Repeat the procedure until the water that flows out of the instrument is perfectly free of residues.

Then, proceed with regular manual cleaning.

Cleaning

Apply automatic or manual cleaning procedures exclusively.

Never use brushes or ultrasonic cleaning.

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Appendix S

Stainless needle holders and stainless steel scissors with tungsten carbide inserts

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Needle holder with tungsten carbide inserts	3000
Scissors with tungsten carbide inserts	3000

SPECIAL PROCEDURES

Decontamination

During the decontamination phase, do not use saline solutions and do not insert the instruments together with others built using base metals. In a saline solution, the presence of instruments coated in noble metals together with others manufactured using base metals would create a galvanic bath with serious, irreversible damages to the noble coating.

Decontamination (through automatic cleaning)

During the rinse phase, initially manually rinse the instruments before placing them inside the thermal disinfectant, opening and closing the instruments or moving the cursor under abundant running water, alternating brushing strokes in the hinged 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.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

Manually rinse the instruments, opening and closing the instruments or moving the cursor under abundant running water, alternating brushing strokes in the hinged 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.

Then, continue with regular manual cleaning.

Appendix T

Hinged stainless steel instruments requiring lubrication, with tungsten carbide inserts

Maximum attainable temperature 180°C ± 3°.

Products	Max number of cycles
Cutters with tungsten carbide inserts	3000

SPECIAL PROCEDURES

Decontamination

During the decontamination phase, do not use saline solutions and do not insert the instruments together with others built using base metals. In a saline solution, the presence of instruments coated in noble metals together with others manufactured using base metals would create a galvanic bath with serious, irreversible damages to the noble coating.

Decontamination (through automatic cleaning)

Initially manually rinse the instruments before placing them inside the thermal disinfecter, opening and closing the instruments or moving the cursor under abundant running water, alternating brushing strokes in the hinged 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.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

Manually rinse the instruments, opening and closing the instruments or moving the cursor under abundant running water, alternating brushing strokes in the hinged 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.

Then, continue with regular manual cleaning.

Maintenance

Immediately following the drying procedure and the visual check, open the instrument all the way and place a few drops of lubricant 8002 or 8010 Rockmed Dental inside the hinge.

The amount of lubricant varies based on the size of the instrument, but excessive dripping must be avoided.

After having applied the lubricant, open and close the instrument about twenty times.

After this procedure, remove any excess lubricant using a clean cloth.

Appendix U

Bimetallic stainless steel instruments coated on the surface – or on part of the surface – with filler metals and Magic Color handle (nylon and aluminum)
Maximum attainable temperature 137°C ± 3°.

Products	Max number of cycles
Heidemann spatulas	200

SPECIAL PROCEDURES

Decontamination

During the decontamination phase, do not use saline solutions and do not insert the instruments together with others built using base metals. In a saline solution, the presence of instruments coated in noble metals together with others manufactured using base metals would create a galvanic bath with serious, irreversible damages to the noble coating.

Cleaning

Apply automatic or manual cleaning procedures exclusively.
Never use brushes or ultrasonic cleaning.

Disinfecting and cleaning

During the drying phase, aim a long jet of compressed air between the metallic part and the plastic part of the instrument in order to prevent stagnant humidity that could cause deterioration both on the metallic and on the plastic part.

Sterilization

Do not exceed max temperature of 137°C.

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Appendix V

Instruments in polypropylene with through-holes

39 Maximum attainable temperature 134°C.

Products	Max number of cycles
Surgical saliva ejectors	100

SPECIAL PROCEDURES

Decontamination (through automatic cleaning)

During the rinse phase, manually rinse the instruments under abundant running water before placing them inside the thermal disinfecter, letting the water enter from an opening in the hole and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air.

Repeat the procedure until the water that flows out of the instrument is perfectly free of residues.

Then, place the instruments in the washer.

Decontamination (through manual cleaning)

If performed completely automatically, manually rinse the instruments, letting the water enter from an opening in the hole using a syringe, and checking that it flows out of the opposite side, alternating flows of water and flows of compressed air.

Repeat the procedure until the water that flows out of the instrument is perfectly free of residues.

Then, proceed with regular manual cleaning.

Sterilization

Do not exceed max temperature of 134°C.

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International Regulations and References

AAMI TIR 12

Design, testing and labelling reusable medical devices for reprocessing in healthcare facilities: A guide for medical device manufacturers

AAMI TIR 30

A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

AAMI TIR 34

Water for reprocessing of medical devices

AAMI TIR 55

Human factors engineering for processing medical devices

ANSI/AAMI ST 77

Containment devices for reusable medical device sterilization

ANSI/AAMI ST 79

Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities

EN 285

Sterilization - Steam sterilizers - Large sterilizers

EN 13060

Small steam sterilizers

ISO 11138-3

Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes

ISO 11140-1

Sterilization of healthcare products - Chemical indicators - Part 1: General requirements

ISO 1607-1

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 15883-1

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests

ISO 17664

Sterilization of re-usable instruments - Information to be provided by the manufacturer for the processing of re-usable instruments

ISO 17665-1

Sterilization of healthcare products, moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 17665-2

Sterilization of health care products, moist heat - Part 2: Guidance on the application of ISO 17665-1

United States Pharmacopoeia (USP)

European Pharmacopoeia (EP)

Japanese Pharmacopoeia (JP)

HTM-01-01

Decontamination of surgical instruments