Reprocessing instructions
for pliers & instruments

Foreword

With appropriate care and maintenance, FORESTADENT medical devices can do their job for many years. Although the constant cleaning and sterilization processes attack the material, observing the following recommendations will prolong the life of your instruments. In addition, proper use will ensure the safety of patients and staff.

The measures specified here are based on the recommendations of the "Kommission für Krankenhaushygiene und Infektionsprävention" (KRINKO) (Commission for Hospital Hygiene and Infection Prevention) at the Robert Koch Institute (RKI) and the "Bundesinstitut für Arzneimittel und Medizinprodukte" (BfArM) (Federal Institute for Drugs and Medical Devices) – Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten (requirements for hygiene in the reprocessing of medical devices) Bundesgesundheitsblatt 2012; 55:1244-1310; DOI 10.1007/s00103-012-1548-6 © Springer-Verlag 2012 – and the Arbeitskreis Instrumenten-Aufbereitung (AKI) (Working Group on Instrument reprocessing) – Instrumenten Aufbereitung in der Zahnarztpraxis (Instrument reprocessing in dental practices) (2016). The user is also recommended to refer to these documents, which contain information on the reprocessing of instruments as well as information on occupational safety and disposal.

Scope of application

This reprocessing instruction applies to reusable, FORESTADENT pliers & instruments.
For accessory products of the OrthoEasy Group please refer to the separate reprocessing instructions.

Scope of the possible cleaning types:

	Manual cleaning & disinfection by ultrasound possible	Ultrasonic pre-cleaning required before automated cleaning and disinfection	Automated Cleaning & Thermal Disinfection	Sterilization
Pliers & Instruments	Yes	Yes	Yes	Yes

Warning notice

General information:

- *National legal regulations, national and international standards and guidelines and the own regulations for hygiene and processing must be complied with.*
- *In case of patients with Creutzfeld-Jakob disease (CJO), suspected CJO or possible variants the applicable national regulations with regard to product reprocessing must be complied with.*
- *If possible, an automated process should be used for cleaning and disinfection of instruments. Due to the significantly lower effectiveness a manual procedure should only be used if an automated procedure is not available; even when using an ultrasonic bath.*
- *It should be noted that the successful reprocessing of medical devices can only be ensured after prior validation of the reprocessing process. The responsibility for this lies with the user/ reprocessor. This applies in particular if the procedures recommended in these reprocessing instructions are deviated from.*
- *Unless otherwise stated on the packaging and/or in the instructions for use, FORESTADENT pliers & instruments must be subjected to basic cleaning and, if necessary, sterilization in accordance with clinical practice standards, even before their first use.*
- *Instruments must not be exposed to temperatures above 141°C (286°F).*
- *Instruments made of stainless steel MUST NOT be reprocessed together with instruments made of base metals in a washer-disinfector, as this can lead to rust formation.*

- *Due to the product design and the materials used, no definitive statement can be made about the lifespan of the products. The lifespan of a product is determined by its function and careful handling. Defective products must run through the entire reprocessing process before being returned and repaired.*

Avoiding fixation of dirt:

Contamination can be fixed to the products in the event of unsuitable treatment. To prevent this, fixating disinfectants (e.g. those with aldehydes) should be avoided, as should pre-cleaning temperatures of >40°C.

Process Chemicals

Stainless steels can be affected by unsuitable chemicals. This can lead to optical changes in the material, including material damage in the form of corrosion and premature ageing. The following points must therefore be observed when selecting cleaning chemicals:

- *In general, the chemicals used for cleaning and disinfection must be suitable for the intended use and compatible with the products to be reprocessed (see manufacturer's instructions of chemical manufacturers).*
- *The chemicals used for reprocessing must be tested and approved (e.g. VAH/DGHM or FDA approval or CE marking) and recommended by the chemical manufacturer with regard to material compatibility. All application specifications of the chemical manufacturer must be strictly adhered to.*
- *Detergents or disinfectants with the following ingredients must not be used:*
  - *Strong bases (> pH 9).*
  - *Organic, mineral and oxidizing acids (< pH 5.5).*
  - *Phenols or iodophores.*
  - *Halogens (chlorine, iodine, bromine).*
  - *Interhalogen compounds/aromatic-/halogenated hydrocarbons/iodophores.*
  - *Strong oxidants/peroxides.*
  - *Organic solvents (e.g. ethers, ketones, benzines).*
- *Overdosage of the chemicals used should be avoided.*
- *Only freshly prepared solutions should be used.*
- *The manufacturer's instructions for the chemicals must be followed.*

The following points must also be observed with regard to the cleaning agents and disinfectants used:

- *The disinfectant used must be bactericidal, fungicidal and virucidal.*
- *Only freshly prepared solutions should be used (solutions should be renewed at least once a day).*
- *Cleaning agents or disinfectants in powder form must be completely dissolved in water before the instruments are immersed in the solution.*
- *Depending on the cleaning/disinfection step, the water quality must be observed when preparing and diluting the cleaning agents or disinfectants.*
- *The manufacturer's specifications for the chemicals must be taken into account. The manufacturer's prescribed exposure times must be observed.*

Materials

Metal brushes or steel wool must not be used for cleaning in order to protect the products to be reprocessed from damage. Only soft brushes or clean soft cloths should be used for manual removal of soiling.

The device used for automatic cleaning and disinfection must always have a tested effectiveness (e.g. DGHM FDA approval, CE marking, in accordance with DIN EN ISO 15883).

Steam sterilizers (in accordance with DIN EN 13060 or DIN EN 285) and the sterilization procedures used (in accordance with DIN EN ISO 17665 / ANSI AAMI ISO 11134) must also have a tested effectiveness.

Storage and transport after use

- *A period of 2 hours should not be exceeded between application and preparation.*
- *Coarse soiling must be removed immediately, within 2 hours at the most. In particular, dental materials adhering to instruments must be removed immediately after use.*
- *Drying or fixing of soiling must be prevented.*
- *The products should be transported dry, contamination protected, in closed containers for cleaning and disinfection.*

Preparation for decontamination

- *If possible, instruments should be disassembled before cleaning.*
- *Drill heads, probes and other sensitive instruments should be prepared in special holders.*

Cleaning & Disinfection

Manual cleaning with ultrasound & disinfection

	Step	Temperature [°C/°F]	time [min]	Concentration	Water quality	Chemistry
Cleaning						
Pre-rinsing	• The contaminated instruments are rinsed under running cold water. • Open and close non-rigid components such as adjusting screws or joints 5 times during rinsing. • If applicable: Rinse the existing cavities of the products at the beginning and end of rinsing with a disposable syringe, if necessary with an attached cannula.	RT (cold)	2	-	Drinking water	-
Soaking 1	• Prepare the cleaning solution according to the manufacturer's instructions for the cleaning chemical. • Immerse products completely in the cleaning solution so that all accessible surfaces are wetted and the products do not touch each other; joint instruments in open position. • Observe the exposure time according to the manufacturer's instructions for the cleaning chemical.	RT (cold)	10	1,5%	Demineralized water	Dr. Weigert – MediClean forte
Intermediate rinsing 1	• Rinse the product completely under cold water so that all accessible surfaces are rinsed. • Move non-rigid components such as adjusting screws or joints during rinsing. • If applicable: Rinse existing product cavities with a disposable syringe, if necessary with an attached cannula. • Allow the products to drip off sufficiently after rinsing.	RT (cold)	1	-	Drinking water	-
Manual cleaning	• Prepare the cleaning solution according to the manufacturer's instructions for the cleaning chemical. • Clean the product with a suitable cleaning brush in the cleaning solution until there are no residues left on the surface. • Move non-rigid components such as adjusting screws or joints during cleaning. • If applicable: Rinse the existing cavities of the products at the beginning and end of the exposure time with a disposable syringe, if necessary with a cannula attached.	RT (cold)	5	1,5%	Demineralized water	Dr. Weigert – MediClean forte

Visual control	• Visual inspection – Repeat the previous steps UNTIL THERE IS NO MORE VISIBLE CONTAMINATION.	-	-	-	-	-
Ultrasonic cleaning	• Prepare the cleaning solution according to the manufacturer's instructions for the cleaning chemical. • Immerse products completely in the cleaning solution so that all accessible surfaces are wetted and the products do not touch each other; joint instruments in open position. • Observe the exposure time according to the manufacturer's instructions for the cleaning chemical.	RT (cold)	15	1,5%	Demineralized water	Dr. Weigert – MediClean forte
Intermediate rinsing 2	• Flush the product completely so that all accessible surfaces are flushed. • Move non-rigid components such as adjusting screws or joints during cleaning. • If applicable: Rinse existing product cavities with a disposable syringe, if necessary with an attached cannula. • Allow the products to drip off sufficiently after rinsing.	RT (cold)	1	-	Demineralized water	-
Disinfection						
Soaking 2	• Prepare the disinfectant solution according to the manufacturer's instructions. • Immerse the products completely in the disinfectant solution so that all accessible surfaces are wetted and the products do not touch each other. • Observe the exposure time according to the manufacturer's instructions for the disinfectant. • Move non-rigid components such as adjusting screws or joints during disinfection. • If applicable: Rinse the existing cavities of the products at the beginning and end of the exposure time with a disposable syringe, if necessary with an attached cannula.	RT (cold)	30	0,75%	Demineralized water	Hartmann AG – Korsolex med AF
Final rinsing	• Rinse product completely with demineralized water so that all accessible surfaces are rinsed. • Move non-rigid components such as adjusting screws or joints during rinsing. • If applicable: Rinse existing product cavities with a disposable syringe, if necessary with an attached cannula. • Allow the products to drip off sufficiently after rinsing.	RT (cold)	1	-	Demineralized water	-
Drying	• Dry with a soft lint-free cloth.	RT	-	-	-	-

Proof of the basic suitability of the manual procedure described here for effective cleaning and disinfection was provided by an independent accredited test laboratory using the specified cleaning agent and an ultrasonic frequency of 40 kH.

Manual pre-cleaning with ultrasound

	Step	Temperature [°C/°F]	Time [min]	Concentration	Water quality	Chemistry
Pre-rinse	• The contaminated instruments are rinsed under running cold water. • Open and close non-rigid components such as adjusting screws or joints 5 times during rinsing. • If applicable: Rinse the existing cavities of the products at the beginning and end of the exposure time with a disposable syringe, if necessary with an attached cannula.	RT (cold)	3	-	Drinking water	-

Ultrasonic cleaning	• Prepare the cleaning solution according to the manufacturer's instructions for the cleaning chemical. • Immerse products completely in the cleaning solution so that all accessible surfaces are wetted and the products do not touch each other; joint instruments in open position. • Observe the exposure time according to the manufacturer's instructions for the cleaning chemical.	RT (cold)	15	1,5%	Demineralized water	Dr. Weigert – MediClean forte
Rinsing	• Rinse product completely with water so that all accessible surfaces are rinsed. • Move non-rigid components such as adjusting screws or joints during rinsing. • If applicable: Rinse existing product cavities with a disposable syringe, if necessary with an attached cannula. • Allow the products to drip off sufficiently after rinsing.	RT (cold)	1	-	Drinking water	-

The basic suitability of the manual procedure described here for effective pre-cleaning prior to automated cleaning and disinfection was demonstrated by an independent accredited test laboratory using the specified cleaning agent and an ultrasonic frequency of 40 kH.

Automated Cleaning & Thermal Disinfection

	Temperature [°C/°F]	time [min]	Concentration	Water quality	Chemistry/Remarks
Pre-cleaning	Cold	2	-	Drinking water	-
Cleaning	55	10	0,5%	Drinking water	Dr. Weigert GmbH – neodisher MediClean forte
Intermediate rinsing	Cold	1	-	Drinking water	-
Neutralization	Cold	1	0,1%	Drinking water	Dr. Weigert GmbH – neodisher Z
Disinfection	93	5	-	-	-
Drying	< 90°C	10	-	-	-

Joint instruments must be treated in a hand-wide open position. Instruments should be introduced into the washer-disinfector in such a way that water can drain from cannulas and blind holes and that they do not touch each other.
Proof of the basic suitability of the automated process described here for effective cleaning and disinfection was provided by an independent accredited test laboratory using the specified detergent and the PG 8582 washer-disinfector (Miele & Cie. KG).

Drying

- *Suitable aids (such as lint-free cloths, compressed air) must be used to dry the products.*
- *93°C shall not be exceeded during drying.*
- *If air is used for drying, care must be taken to ensure that it is filtered.*
- *Drying and post-drying must take place in a clean place.*

Inspection

- *After cleaning and disinfection, the visible surfaces must be checked for residues. Instruments that are still dirty must be cleaned and disinfected again.*
- *After cleaning and disinfection, all products must be checked for corrosion, damaged surfaces, loose screws, springs and working ends, splinters and impurities, as well as firm seating of carbide plates.*
- *The function of the products must also be checked (e.g. ease of movement of joint instruments).*
- *Corroded, damaged or defective products must be discarded.*

Care & Repair

Joint instruments must be maintained with a lubricant suitable for sterilisation (and for the sterilisation temperature) (e.g. medical white oil), which has a tested biocompatibility. Only the moving parts are treated, not the entire product. The lubricant must be distributed evenly by moving the joints. Excess lubricant should be removed with a lint-free cloth.

Packaging

- *The instruments must be packed immediately after cleaning and disinfection has been completed.*
- *Disassembled instruments are reassembled for this purpose.*
- *The use of sterilization trays is recommended.*
- *Joint instruments must be packed and sterilized in a hand-wide open position.*
- *The packaging must be suitable for steam sterilization (according to DIN EN ISO/ANSI AAMI ISO 11607) and large enough for the product to be sterilized.*

Steam sterilization

The basic suitability of the sterilization process described here has been demonstrated by an independent accredited test laboratory, using an autoclave 25 (MELAG Medizintechnik oHG).

- *Fractionated vacuum process.*
- *134°C, holding time 5 min.*
- *Drying at least 20 min.*
- *Joint instruments must be treated in a hand-wide open position.*
- *Instruments must not touch each other.*
- *Furthermore, the manufacturer's instructions for the sterilization device must be observed, as well as the applicable standards (DIN EN 13060 or DIN EN 285, DIN EN ISO 17665).*

Storage

- *The instruments must be dry for storage.*
- *After sterilization, the products must be stored in a dry, dust-free place at a consistent room temperature and humidity (avoid fluctuations).*
- *Closed storage systems are to be preferred in order to provide additional protection against contamination.*
- *Sterile and non-sterile products should not be stored together.*
- *Instruments must be stored in such a way that mutual damage is excluded.*
- *The products must not be stored in the immediate vicinity of chemicals that may release corrosive vapors due to their contents.*

THE REPROCESSOR IS RESPONSIBLE FOR ENSURING THAT THE REPROCESSING ACTUALLY CARRIED OUT WITH THE EQUIPMENT, MATERIALS AND PERSONNEL USED IN THE REPROCESSING FACILITY ACHIEVES THE DESIRED RESULTS. THIS USUALLY REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS. SIMILARLY, ANY DEVIATION FROM THE INSTRUCTIONS PROVIDED SHOULD BE CAREFULLY EVALUATED BY THE REPROCESSOR FOR EFFECTIVENESS AND POSSIBLE ADVERSE CONSEQUENCES.

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