# Reprocessing instructions
## for molar bands & attachments

## Foreword

*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

*Molar bands and attachments can be reprocessed according to these reprocessing instructions after the fitting on the patient. Molar bands and attachments that have been used in the course of a treatment are still considered disposable products and must NOT be reprocessed.*

*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 |
|---|---|---|---|---|
| Molar bands and attachments | No | No | 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 the case of patients with Creutzfeldt-Jakob disease (CJD), suspected CJD 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.*
- *Products must not be exposed to temperatures above 141°C (286°F).*
- *Proucts 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 products 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 us*

- *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 productss 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.*

# *Cleaning & Disinfection*

## *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 | - | - | - |

*Products 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. Products 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.*
- *Corroded, damaged or defective products must be discarded.*

# *Packaging*

- *The products must be packed immediately after cleaning and disinfection has been completed.*
- *The use of sterilization trays is recommended.*
- *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.*
- *Products 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, DIN EN ISO 11135).*

# Storage

- *The products 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.*
- *Products 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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