

Reprocessing of KKD Dental Hand Instruments incl. rubber dam clamps ACC. TO EN ISO 17664

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1.0 Fundamental points

All instruments are to be cleaned, disinfected, and sterilized prior to each use. In addition, cleaning, disinfection and sterilization is also required for the first use of non-sterile instruments after removal from the protective packaging. Effective cleaning and disinfection is an indispensable requirement for proper instrument sterilization.

The user is responsible for the sterility of the instruments. Therefore, please ensure that only validated procedures are used for cleaning, disinfection and sterilization. The sterilization equipment must also be maintained and checked regularly, as well as the validated parameters applied to each cleaning and sterilization cycle.

Additionally, consider the legal provisions valid for your country as well as to the hygienic instructions of the doctor's practice or hospital.

2.0 Instrument Reprocessing Steps

2.1 Cleaning and Disinfection

2.1.1 Basics

If possible, an automatic procedure in a Washer / Disinfector unit should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of a ultrasonic bath – should only be used if an automatic procedure is not available or if such a method is not compatible with specific materials; in this case, the significantly lower efficiency of a manual procedure must be considered. The pre-treatment step is to be performed in both cases.

All assembled instruments must be disassembled before

Protection of Staff Members:

All used and contaminated Instruments must be handled with protective gloves fulfilling the requirements of Directive 89/686/EEC. Contaminated Instruments must be disinfected as early as possible in the reprocessing process, in order to maximize safety for staff members when handling contaminated instruments.

2.1.2 Pre-treatment

Before processing the instruments single or in a tray or cassette system, remove coarse impurities on the instruments immediately after application (within a maximum of 2 h). Instruments with impurities have to be pre-treated within two hours from the application.

If rubber dam clamps had contact with sodium hypochlorite, it's necessary to clean with fresh water immediately.

Use a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood impurities could occur), possess a fundamentally approved efficiency (i.e. DGHM, RKI approval or CE marking), be suitable for the disinfection of instruments and be compatible with the instruments (see 2.7 Material resistance section). For cleaning agents and disinfectants the instructions of the manufacturer must be observed. For manual removal of coarse impurities use only a soft brush or a long handled soft brush, but in no case metal brushes or steel wool.

If applicable: Rinse all lumens of the instruments five times with a single-use syringe (minimum volume 50 ml) or a suitable rinsing adapter.

Consider, that the disinfectant used in the pre-treatment step serves only for personal safety and cannot replace the disinfection step, which should be performed later.

2.1.3 Automatic Cleaning / Disinfection in a Washer-Disinfector unit

Consider the following items, when using a Washer-Disinfector unit:

- fundamentally approved efficiency of the Washer-Disinfector unit (for example EN ISO 15883, DGHM approval and/or CE marking)
- possibility for an approved program for thermal disinfection (A 0 >3000 or in case of older devices at least 10 min at 93°C and must follow equipment manufacturers guidelines). In the case of chemical disinfection there is a danger of remnants of the disinfectant on instruments
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post rinse only with low contaminated and deionized water (max. 10 germs/ml, max. 0.25 endotoxin units/ml) (highly purified water acc. Pharmacopeia).
- only use filtered air for drying-regular maintenance and inspection/calibration of the Washer-Disinfector unit.

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For the selection of detergents to be used with the Washer-Disinfector unit, consider the following items:

- fundamental suitability for cleaning of instruments
- additional application – if instruments are not compatible with the thermal disinfection please follow the recommended instructions for the manual cleaning and disinfection
- compatibility of the detergents with the instruments (see 2.7 Material resistance)

Consider the instructions of the detergent manufacturers regarding concentration and soaking time.

Procedure:

1. Completely disassemble instruments if applicable.
2. Place the disassembled instruments in a cassette or any other tray system suitable for the instrument and place it in the Washer-Disinfector unit (no contact between the instruments). If applicable: Connect the instruments to the rinsing port of the Washer-Disinfector unit.
3. Start the program.
4. Remove the instruments from the Washer-Disinfector unit after end of the program.
5. Inspect and package the instruments immediately after removal (see sections 2.2 Inspection, 2.3 Maintenance, and 2.4 Packaging, if necessary allow post drying step in a clean place).

The fundamental suitability of the instruments for an effective automatic cleaning and disinfection was demonstrated by an independent accredited test laboratory by application of the disinfectant G 7882, Miele & Cie. GmbH & Co, (thermal disinfection) and the cleaning detergent Neodisher MediClean forte.

2.1.4 Manual and Ultrasonic Cleaning and Disinfection

2.1.4.1 General information

Consider the following items during selection of the cleaning and disinfection detergents:

- fundamental suitability for the cleaning and disinfection of dental instruments
- application of a disinfectant with approved efficiency (for example VAH / DGHM, RKI approval or CE marking) compatible with the cleaning detergent used.
- compatibility of the detergents used with the instruments (see 2.7 Material Resistance)
- Powder based cleaners or disinfectants have to be dissolved completely in water before immersing the instruments into the solution.
- Observe the instructions of the manufacturer with respect to the concentration of the cleaning/disinfectant solution, the time of exposure and the temperature.

2.1.4.2 Manual Cleaning and Disinfection

Procedure:

Cleaning

1. Completely disassemble the instruments, if applicable.
2. Soak the disassembled instruments for the recommended soaking time in the cleaning solution and make sure that the instruments are sufficiently immersed. If applicable: Rinse all lumens of the instruments five times at the beginning and at the end of the soaking time with a single-use syringe (minimum volume 50 ml) or a suitable rinsing adapter.
3. Remove the instruments from the cleaning solution and post rinse them intensively with low contaminated and deionized water.
4. Inspect the instruments for proper cleaning.

Disinfection

5. Soak the disassembled instruments for the given soaking time in the disinfectant solution so that the instruments are sufficiently immersed. If applicable: Rinse all lumens of the instruments five times at the beginning and at the end of the soaking time with a single-use syringe (minimum volume 50 ml) of a suitable rinsing adapter.
6. Remove the instruments from the disinfectant solution and post rinse them five times with low contaminated and deionized water.
7. All instruments must be completely dry before packaging (If necessary allow post drying in a clean place).
8. Perform inspection and maintenance of the instruments (see 2.2 Inspection and 2.3 Maintenance sections).
9. Package the instruments immediately

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The fundamental suitability of the instruments for an effective cleaning and disinfection was demonstrated by an independent accredited test laboratory by application of the cleaning detergent and the disinfectant ID 212 (DÜRR Dental AG, Bietigheim) considering the specified procedure

2.2 Inspection

Inspect all instruments after the cleaning and disinfection step for corrosion, damaged surfaces, and impurities. Do not further use damaged instruments (for limitation of the numbers of re-use cycles, see 2.8 Reusability section). If instruments are still dirty, clean and disinfect again. Resharpen instruments if necessary. Completely remove any residues from the sharpening process, such as metal residue or sharpening oil.

2.3 Maintenance

Assemble disassembled instruments if necessary. If the corrosion cannot be completely eliminated, the instruments should be removed from use. Otherwise such corrosion could damage other instruments. After treating an instrument, the instrument must be cleaned and sterilized once more. Hinged instruments have to be lubricated with a lubricant suitable for steam sterilization, like KKD Silikonspray.

2.4 Packaging

We recommend suitable sterilization containers, if the following requirements are fulfilled:

- Conformity with EN ISO/ANSI AAMI ISO 11607-1 and 2 and valid parts of EN 868
- suitable for steam sterilization (temperature resistance up to at least 141 °C (286 °F), sufficient steam permeability)
- sufficient protection of the instruments and the sterilization packaging against mechanical damage
- regular maintenance according to the manufacturers instructions

2.5 Sterilization

Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user.

2.5.1 Steam sterilization

- fractionated vacuum or gravity¹ procedure (with sufficient product drying)
- steam sterilizer according to EN 13060 and EN 285
- validated according to EN ISO/ANSI AAMI ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification(PQ))
- maximum sterilization temperature 138 °C (280 °F); plus tolerance according to EN ISO/ANSI AAMI ISO 17665
- sterilization time (exposure time at the sterilization temperature) at least 20 min at 121 °C (250 °F) or 5 min at 132 °C (270 °F)/134 °C (273 °F)

¹If possible, a fractionated vacuum procedure should be used for sterilization of the instruments. A gravity procedure should only be used if a fractionated vacuum procedure is not available; in this case, the significantly lower efficiency of a gravity procedure has to be considered.

The fundamental suitability of the instruments for effective steam sterilization was demonstrated by an independent accredited test laboratory by application of the steam sterilizer Melag Vacuklav 40-B (MELAG Medizintechnik oHG, Berlin), fractionated vacuum procedure, as well as the specified procedure.

2.5.2 Inspection and Maintenance Recommendations for Steam Sterilizers:

- The manufacturers instructions with respect to routine inspection and the regular maintenance of the Sterilizer must be observed.
- The sterilizer must be cleaned on a regular basis.
- Only low contaminated and deionized water should be used.
- The sterilized items have to be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

2.5.3 Restrictions:

- The flash sterilization procedure must not be used.
- Do not use radiation sterilization, formaldehyde sterilization, ethylenoxide sterilization, or plasma sterilization.
- The application of dry heat sterilization is the responsibility of the user.

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2.6 Storage

Please store the instruments after sterilization in a dry and dust free place. Sterilization can only be maintained, if the instruments remain packaged or wrapped - impermeable to micro-organisms - following validated standards. The status of the sterilization has to be clearly indicated on the wrapped packages or the containers. For safety reasons, keep sterile and non-sterile instruments strictly apart.

2.7 Material resistance

Detergents or disinfectants containing the following substances must not be used:

- strong alkalines (> pH 9)
- strong acids (< pH 4)
- phenols or iodophors-interhalogenic agents/halogenic hydrocarbons/iodophors
- strong oxidizing agents/peroxides-organic solvents

Do not clean any instruments, sterilization trays or sterilization containers using metal brushes or steel wool. Do not expose any instruments, cassettes, trays or sterilization containers to temperatures higher than 141 °C (286 °F)! Exposure to higher temperatures is the responsibility of the user. Water quality may influence the result of the cleaning and disinfection of the instruments. **Corrosion could be caused by high contents of chloride or other minerals in the tap water.** If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in your area. With the use of completely deionized or distilled water most water quality problems can be avoided beforehand.

2.8 Reusability

The instruments can be reused, unless indicated otherwise. The life time of instruments depends on the frequency of use, the care of the user and proper reprocessing methods. The user is responsible for inspecting instruments prior to each use, and for the use of damaged and dirty instruments (no liability in case of disregard).

Other free information available for download:

Instrument reprocessing in Dental Practices how to do it right
<http://www.a-k-i.org/aki-brochures/yellow-brochure/?L=1>