Preparation and Reprocessing Instructions in accordance with DIN/EN ISO 17664

Polishers

MANUFACTURER	METHOD	SYMBOL	REV. STATUS	LANGUAGE
CB Healthcare Consulting GmbH Am Neumarkt 34, 22041 Hamburg, Germany Distributed by: Clinician's Choice Dental Products, Inc	H	H	09	English en

WARNINGS:

- Observe the manufacturer's information on material compatibilities for cleaning, disinfection and sterilisation.
- All instruments are delivered unsterile and must go through the indicated cycle before and after each use.
- Strong acids and strong bases may oxidise the stainless steel shank.
- Avoid temperatures >150 °C.
- Ultrasonic bath must not exceed temperatures of 42 °C because of the possible coagulation of protein.
- Instruments that have not completely dried after cleaning and disinfection must be dried again (e.g. with medical compressed air) to avoid compromising the success of sterilisation.
- Instructions of cleaning and/or disinfecting solutions must specifically state **"suitable for rubber polishers or synthetics/silicones"**. The exposure time and concentration specified by the manufacturer must be followed.

RESTRICTION OF REPROCESSING:
Repetitive reprocessing can slightly change both the look and feel of the product, but does not interfere with the instrument's function.

RISK ASSESSMENT AND CLASSIFICATION OF MEDICAL DEVICES BEFORE REPROCESSING:
The type and scope of reprocessing is determined by the use of the medical device. Therefore, the operator is responsible for the correct classification of the medical devices and thus for the definition of the type and scope of reprocessing (see KRINKO/BfArM recommendation, point 1.2.1 Risk assessment and classification of medical devices prior to reprocessing). On the basis of this user-dependent classification, the operator can determine which of the reprocessing methods listed in this preparation and reprocessing instruction needs to be applied.

PLACE OF USE:	No special requirements
STORAGE AND TRANSPORT:	It is recommended to transport the contaminated instruments in a closed container. It is recommended that instruments be reprocessed as soon as possible, within 2 hours after use at the most. Intermediate storage of used instruments with contamination such as blood residues can lead to corrosion damage.
PREPARATION:	Wear personal protective equipment (durable gloves, water-repellent coat, face protection mask or goggles and protection mask).
PRE-TREATMENT:	Pre-clean under running water with a brush (plastic) directly after use. **Equipment:** Plastic brush (e.g. Interlock, #09084), tap water (20± 2 °C) (at least drinking water quality) 1. Rinse the polishers under running water for 60 seconds and brush them thoroughly with a plastic brush, particularly the difficult to access areas of the head (bristles, silicone bristle tips).
CLEANING: MANUAL	**Note:** Coarse surface contamination on the instruments must be removed **before manual reprocessing** (see pre-treatment) **Equipment:** Multi-stage enzymatic cleaner (e.g. Dürr Dental, ID 215), tap water/flowing water (20± 2 °C) (at least drinking water quality), ultrasonic bath (e.g. Sonorex Digital 10P) 1. Prepare the cleaning solution according to the manufacturer's instructions (Dürr Dental ID 215 2% solution was validated) and fill into an ultrasonic bath. 2. Completely immerse the polishers in the solution. 3. Expose the products for 1 minute to the ultrasonic bath. 4. Remove the polishers from the cleaning solution and rinse them each thoroughly (30 seconds) under running water. 5. Check for cleanliness. If contamination is still visible, repeat the above specified steps.
DISINFECTION: MANUAL (with subsequent sterilisation)	**Equipment:** At least limited virucidal instrument disinfectant (VAH listed - or at least listed in the IHO with testing according to DVV) e.g. based on quaternary ammonium compound(s), alkylamine(s)/alkylamine derivative(s), guanidine(s)/guanidine derivative(s) (e.g. Dürr Dental, ID 212), preferably fully deionised water (deionised water, according to KRINKO/BfArM recommendation free of facultatively pathogenic microorganisms), ultrasonic bath (e.g. Sonorex Digital 10P), lint-free sterile cloth. 1. Prepare the disinfectant solution according to the manufacturer's instructions (Dürr Dental ID 212, 2% solution was validated) and place into an ultrasonic bath. 2. Completely immerse the polishers in the disinfectant solution. 3. Expose the products for 2 minutes to the ultrasonic bath. 4. Further exposure time to the disinfectant solution for 5 minutes according to the desinfectant manufacturer's instructions. 5. Remove the polishers from the disinfectant solution and allow to drip off. 6. Rinse the products with deionised water for 30 seconds. 7. Wipe with a single use sterile lint-free cloth or, if necessary, dry with medical compressed air.

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CLEANING AND DISINFECTION: AUTOMATIC

Note: Coarse surface contamination on the instruments must be removed **prior to automatic reprocessing** (see pre-treatment)

Equipment: Cleaning and disinfection unit according to DIN EN ISO 15883-1+2 with thermal programme (temperature 90 °C to 95 °C), detergent: mildly alkaline detergent (e.g. Dr. Weigert neodisher MediClean Dental)

1. Place the instruments in a suitable small parts tray or on the load carrier such that all surfaces of the instruments are cleaned and disinfected.
2. Close WD and start programme, see table below for programme sequence.

PROG. STEP	WATER	DOSAGE	TIME	TEMPERATURE
Pre-rinse	CW		5 min	
Dosage of detergent		According to manufacturer's instructions		According to manufacturer's instructions
Clean	Fully deionised water		10 min	55 °C
Rinse	Fully deionised water		2 min	
Disinfect	Fully deionised water		3 min	Ao-value > 3000[1] (e.g. 90 °C, 5 min)
Drying			15 min	up to 120 °C

[1] Authorities may issue other operational regulations (disinfection performance parameters) in their area of competence.

3. Remove the instruments at the end of the programme.
4. Check that the load is dry and, if necessary, dry with medical compressed air.
5. Visual inspection for cleanliness is performed after removal from the WD. If contamination is still visible, reclean medical devices again manually. Subsequently, the recleaned medical devices must again be reprocessed automatically.

MAINTENANCE, INSPECTION AND CHECK:

Equipment: Illuminated magnifying glass (3-6 dioptres)

All instruments must be inspected visually for cleanliness, integrity and functionality, if necessary by using an illuminated magnifying glass (3-6 dioptres).

All instruments are to be checked for damage and wear. Damaged medical devices may no longer be used and must be sorted out.

PACKAGING:

Equipment: Film-paper packaging (e.g. steriCLIN, art. no. 3FKFB210112 and 3FKFB210140), sealing device (e.g. HAWO, type 880 DC-V)

A suitable method (sterile barrier system) is to be used to package the instruments. Packaging according to DIN EN ISO 11607.

A sterile barrier system (e.g. film-paper packaging) according to DIN EN ISO 11607 is to be used, which is intended for steam sterilisation by the manufacturer. The instruments are double packed. The packaging must be large enough to avoid stressing the sealing seam.

Note: After the heat sealing process, the sealing seam must be checked visually for any defects.
In case of defects, the packaging must be opened and the instrument repacked and sealed.

STERILISATION:

Device: Steriliser according to DIN EN 285 or small steam steriliser according to DIN EN 13060, type B process

Process: Steam sterilisation with fractionated pre-vacuum, 134 °C, holding time min. 3 min (in Germany according to KRINKO/BfArM recommendation 134 °C min. 5 min) or 132 °C min. 3 min (parameter of validation). Longer holding times are possible.

1. Place the packaged products in the sterilisation chamber
2. Start the programme.
3. Remove the products at the end of the programme and allow to cool down.
4. Then check the packaging for possible damage. Faulted packaging must be regarded as being non-sterile. The instruments must be repacked and sterilised.

STORAGE:

Duration of storage according to own specifications.

It is recommended to store instruments packed and protected from recontamination in proven suitable sterile packaging, cassettes or retainers.

ADDITIONAL INFORMATION:

none

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