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## Manufacturer information

for re-processing resterilisable instruments in the dental practice for users with appropriate qualification according to DIN EN ISO 17664.

# Medical devices semi-critical B / Non-invasive use

**Products:**
Instruments, which come into contact with mucosa or pathologically changed skin. This manufacturer information applies for all dental instruments supplied by Edenta, which are used for the following non-invasive procedures (preventive/ restorative/ dental prosthetic/ orthodontic treatments) as well as instruments for podiatry. These include polishers, ceramic rotary instruments, tungsten carbide, steel and diamond rotary instruments used for cavity and crown preparations, filling removal and preparation or crown cutting.

**Important information:**
New instruments supplied non-sterile must be processed before first use. Alkaline solutions should not be used for disinfecting polishers and ceramic rotary instruments. Observe the manufacturer's specifications regarding concentration and reaction time. Single-use products identified on the packaging with ⊗, can only be disinfected manually (not suitable for CDM or steam steriliser) using a suitable disinfectant (e.g. HELVEMED Instrument Forte). FlexiSnap mandrels are reusable, suitable for CDM and steam sterilisable. Colour-anodised aluminium units (e.g. bur block 40500 to 40580 and Retopin mandrel) lose their colour during use of standard cleaning procedures and in a CDM. Cleaning and disinfectant agents, specifically designed for these instruments should be used during processing (e.g. HELVEMED Instrument Thermo EC). Tool steel instruments (steel burs) are unsuitable for both mechanical processing and steam sterilisation and can only be disinfected manually using a suitable disinfectant (e.g. HELVEMED Instrument Forte). It is recommended to change to a suitable tungsten carbide instrument.

**Re-processing limits:**
The following figures are empirical values for the re-processability (product service life) of the following listed instrument groups:

| | | | |
|---|---|---|---|
| Stainless steel instruments: | - 10x | Diamond instruments: | - 10x |
| Tungsten carbide instruments / ceramic: | - 15x | Polishers / ceramic abrasives: | - 10x |

Repeated reprocessing has no effect on instrument performance as all the materials of these instruments allow for multiple reprocessing. The end of the product's service life is generally determined by wear and damage due to use of the instruments. The end of the product's service life (time when re-processing cannot be regarded as safe) is defined by defective instruments (missing diamond coating, blunt/chipped blades, fractured working sections, corroded surfaces, bent instruments etc.) The end of the product's service life should be guaranteed by the personnel preparing (with special training), who should discard defective instruments. This ensures that only instruments, which are undamaged mechanically, are safely and reproducibly processed using appropriate processing.

Single-use products (identified on the packaging with ⊗ ) are not approved for reuse. Safe use cannot be guaranteed if these products are reused, as there is the risk of infection and/or the products are no longer safe to use.

**Workplace:**
Hygienic procedures according to country-specific guidelines.

**Storage / Transport:**
Immediately after use, place the instruments in a suitable (alkali-free and aldehyde-free) cleaning/disinfection solution (e.g. in a bur cleaning stand) and reprocess after a maximum of one hour. Observe the manufacturer's specifications regarding concentration and reaction time. Instruments should be transported to the processing area in the bur cleaning stand.

**Cleaning and disinfection:**
According to the recommendation of the German Commission for Hospital and Infectious Diseases Prevention (KRINKO) and the Robert Koch Institute (RKI) further mechanical processing and thermal disinfection are preferred.

## Validated mechanical processing

**Equipment used:**

Steelco DS500CL washer disinfector (CDM); Programme 1 instruments Ao value 3000; cleaning agent: Borer Chemie deconex PROZYME ALKA - 5mL/L - 35°C, Borer Chemie deconex NEUTRADRY – 0.7mL/L - 90°C; bur blocks for rotary instruments (e.g. Edenta Ref. 40600 – 40603).

| Steps | Program - step | EF | EC | ED | MAX. Temp. °C | Temps de maintien | Dosage Temp. °C | Dosage I | Dosage II |
|---|---|---|---|---|---|---|---|---|---|
| 1 | *Pré-lavage 1* | ☒ | ☐ | ☐ | 25°C | 1 min | | | |
| 2 | *pré-lavage 2* | ☒ | ☐ | ☐ | 25°C | 2 min | | | |
| 3 | *lavage 1* ☐ *sans vidange* | ☐ | ☐ | ☒ | 45°C | 3 min | 40°C | 6ml/l. | |
| 4 | *lavage 2* ☒ *même eau que lavage 1* | ☐ | ☐ | ☒ | 55°C | 6 min | | | |
| 6 | *rinçage 1* | ☒ | ☒ | ☐ | 45°C | 1 min | | | |
| 7 | *rinçage 2* | ☐ | ☐ | ☒ | 25°C | 1 min | | | |
| 8 | *Désinfection thermique rinçage final* | ☐ | ☐ | ☒ | 90°C | 5 min | 90°C | | 0.4ml/l. |
| 10 | *Séchage* | | | | 110°C | 16min | | | |
| 11 | *Refroidissement* | | | | 30°C | 2 min | | | |

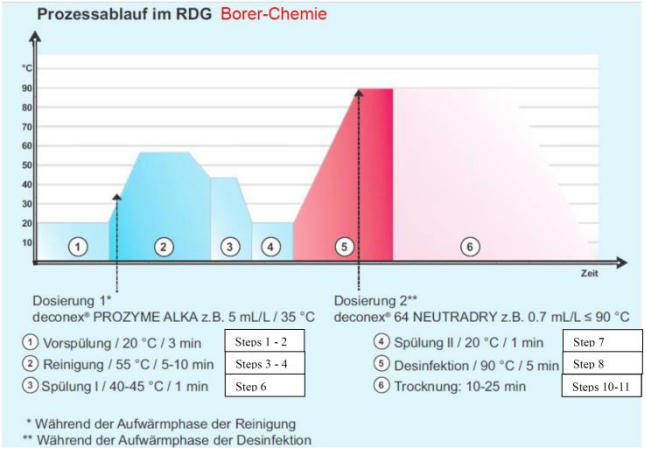


**Fig. 1** **schematic sequence of Programme 1 instruments Ao value 3000**

**Processing:**

1. Remove instruments from the bur cleaning stand or interim bur blocks immediately before mechanical processing. Rinse off any contamination adhering to the instruments under clean running water using a hard plastic brush. Rinse the instruments under clean running water before mechanical processing to ensure no residue of the cleaning/disinfection agent gets into the machine.
2. Instruments should not come into contact with each other during cleaning, therefore, place them in a suitable bur block.
3. Place the bur blocks in the CDM and position, so that the spray jet hits the instruments directly.
4. Insert cleaning agent (e.g. PROZYME ALKA - 5mL/L - 35°C / NEUTRADRY – 0.7mL/L - ≤ 90°C) into the machine according to the instructions on the product label and CDM manufacturer's specifications.
5. Start Programme 1 instruments Ao value 3000 for thermal disinfection; see Fig. 1 for programme sequence. Thermal disinfection is completed taking into account national regulations and Ao value (EN/ISO 15883).
6. The use of fully desalinated water (FD-W) is recommended in the final rinse phase to prevent staining.
7. Remove the instruments from the CDM after the programme sequence is complete and dry – in accordance with RKI recommendation preferably using clean, dry compressed air.
8. Check visually for cleanness and integrity (e.g. using a watchmaker's eye loupe etc. with 8 to 10 x magnification). Discard defective instruments (missing diamond coating, blunt/chipped blades, fractured working sections, corroded surfaces, bent instruments etc.). If there is visible residual contamination, repeat cleaning and disinfection until contamination is no longer visible. Instruments should be discarded if contamination is still visible following repeated cleaning and disinfection.

## Standard manual processing (alternative)

**Equipment used:**

Plastic brush

Suitable cleaning and disinfection agent (e.g. HELVEMED Instrument Forte) with disinfection verification for rotary instruments.

Ultrasonic cleaner/ Instrument disinfectant

**Processing:**

1. Remove instruments from the bur cleaning stand or interim bur blocks immediately before manual processing and rinse off any surface contamination adhering to the instruments under clean running water using a hard plastic brush.
2. Instruments should not come into contact with each other during cleaning, therefore, place them in a suitable bur block in the ultrasonic cleaner filled with cleaning and disinfection agent.
3. As the oscillations in the ultrasonic cleaner can be absorbed by materials of polishers and ceramic rotary instruments, these instruments should only be processed in the instrument disinfectant.
4. For cleaning and chemical disinfection in the ultrasonic cleaner observe the cleaning/disinfection agent manufacturer's specifications regarding concentration and reaction time (e.g. HELVEMED Instrument Forte 20mL/L – 15 min.). The reaction time only starts once the last instrument has been placed in the ultrasonic cleaner and should not be reduced. Clean at max. 45°C (risk of protein coagulation).
5. Once the reaction time is complete, thoroughly rinse off any disinfection agent residue on the instruments under clean running water (use of fully desalinated water (FD-W) in the final rinse phase prevents staining).
6. Dry instruments – according to RKI recommendation (preferably using clean, dry compressed air)

7. Check visually for cleanness and integrity (e.g. using a watchmaker's eye loupe etc. with 8 to 10 x magnification). Discard defective instruments (missing diamond coating, blunt/chipped blades, fractured working sections, corroded surfaces, bent instruments etc.). If there is visible residual contamination, repeat cleaning and disinfection until contamination is no longer visible. Instruments should be discarded if contamination is still visible following repeated cleaning and disinfection.

**Steam sterilisation:**

**Note:** With verifiable disinfection in a CDM (validated mechanical processing) the following sterilisation in a steam steriliser can be omitted.

**Note:** With manual processing (standard manual processing) of instruments the following sterilisation in a steam steriliser must be completed.

**Steam sterilisation in the fractional vacuum procedure with validated process**
(Machine compliant with EN 13060, Class B)


- Instruments unpacked in suitable bur block.
- Fractional pre-vacuum (4 x).
- Sterilisation temperature 134 °C / 2.1 bar.
- Hold time 5 minutes (full cycle).
- Drying time 10 minutes.

To avoid staining and corrosion the steam must be free of particles. The recommended limit (see table Fig. 2) of particles for feed water and steam condensate is defined by standard DIN EN 13060. When sterilising several instruments, the maximum loading capacity of the steam steriliser should not be exceeded. Observe the machine manufacturer's specifications.

Documented approval after successfully completed sterilisation.

**Transport and storage:**
Instruments should be transported and stored clean, protected from dust, moisture and recontamination maintaining the storage times valid in the respective country. Instruments should always be protected against chemicals, acids, heat and extreme temperature fluctuations.

**Material resistance:**
Ensure when selecting cleaning and disinfection agents that they do not contain the following ingredients: organic, mineral or oxidising acids/ strong alkalis (pH > 10.5 not permitted, only neutral or weak alkaline cleaning agent recommended) / do not use alkaline cleaning agent for polishers / alcohols, ethers, ketones, benzines / oxidants. Never clean any instruments or sterilisation trays using metal brushes or steel wool.

The manufacturer guarantees that the processing procedures presented above are suitable for processing the named instrument group for reuse. The person processing the instruments is responsible for ensuring that the actual re-processing with the equipment, materials and personnel used in the re-processing facility achieves the desired results. Routine checks of the validated mechanical and standard manual processing procedures are normally required for this. Any deviation from the procedures presented here (e.g. use of other process chemicals) should also be carefully evaluated by the person processing the instruments for their effectiveness or possible detrimental consequences.

Observe the valid legal regulations in the respective country for re-processing medical products
(e.g. www.swissmedic.ch)

Fig. 2 Contamination in the condensate and feed water

| | Feed water | Condensate |
|---|---|---|
| Steam residue | ≤ 10 mg/l | ≤ 1,0 mg/l |
| Silicon oxide, $SiO_2$ | ≤ 1 mg/l | ≤ 0,1 mg/l |
| Iron | ≤ 0,2 mg/l | ≤ 0,1 mg/l |
| Cadmium | ≤ 0,005 mg/l | ≤ 0,005 mg/l |
| Lead | ≤ 0,05 mg/l | ≤ 0,05 mg/l |
| Heavy metal traces, except iron, cadmium, lead | ≤ 0,1 mg/l | ≤ 0,1 mg/l |
| Chloride | ≤ 2 mg/l | ≤ 0,1 mg/l |
| Phosphate | ≤ 0,5 mg/l | ≤ 0,1 mg/l |
| Conductivity (at 20 °C) | ≤ 15 µS/cm | ≤ 3 µS/cm |
| pH | 5 to 7,5 | 5 to 7 |
| Appearance | colourless, clear, without sediments | colourless, clear, without sediments |
| Hardness | ≤ 0,02 mmol/l | ≤ 0,02 mmol/l |
| NOTE: The condensate formed from the steam which originated from the empty steriliser chamber | | |