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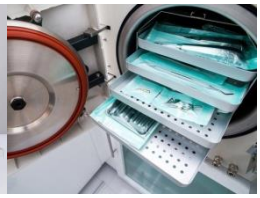

Manufacturer information

for the reprocessing of resterilisable instruments in the dental practice for users with the appropriate qualification in accordance with DIN EN ISO 17664.

Medical devices Critical B / Invasive use

Products:
Instruments that penetrate the skin or mucous membrane and come into contact with blood, internal tissues or organs, including wounds. This manufacturer's information applies to all dental instruments supplied by Edenta that are used for surgical or endodontic procedures. These are diamond and tungsten carbide instruments, stainless steel instruments and root canal instruments made of stainless steel or nickel-titanium.

Important notes:
New, non-sterile instruments supplied must be reprocessed before first use. Colour-anodised aluminium parts (e.g. Bur block 40500 to 40580 and Retopin Mandrel) lose their colour when using standard cleaning processes and in the washer-disinfector. Specially formulated cleaning agents and disinfectants (e.g. HELVEMED Instrument Thermo EC) must be used during reprocessing. Observe the manufacturer's instructions for concentration and contact time. Endo stoppers must be removed from the root canal instruments before reprocessing.

Limitation of reprocessing:
The following values are empirical values for the reusability (product service life) of the instrument groups listed below:

Stainless steel instruments:	- 10x	Endo instruments:	wide channels	- max. 6x
Tungsten carbide instruments / ceramics:	- 15x		medium-sized channels	- max. 3x
Diamond instruments:	- 10x		narrow channels	use only once

Repeated reprocessing has no influence on the instrument performance, as all materials of these instruments allow multiple reprocessing. The end of the product's service life is basically only determined by wear and damage caused by the use of the instruments. The end of the product service life (time at which reprocessing can no longer be considered safe) is defined by defective instruments, e.g. with missing diamond coating, blunt/broken cutting edges, fractured working parts, corroded surfaces, bent instruments, etc.). The end of the product's service life is guaranteed by the reprocessor (with special training), who sorts out the defective instruments. This ensures that only instruments that are mechanically undamaged can be reprocessed safely and reproducibly with appropriate reprocessing.
Single-use articles (labelled on the packaging with ⊗) are not approved for reuse. Safe use cannot be guaranteed if these products are used again, as there is a risk of infection and/or the safety of the products is no longer guaranteed.

Workplace:
Effective hygiene measures in accordance with country-specific requirements.

Storage / Transport:
Immediately after use, place the instruments in a suitable (alkaline, aldehyde-free) cleaning/disinfection solution (e.g. neodisher® Septo PreClean, in a disinfection container for burs) and reprocess them after one hour at the latest. Special care must be taken when cleaning internally cooled instruments. Thoroughly rinse internally cooled instruments with fully demineralised (DI) water. If the cooling holes are not free, replace the instrument. Observe the manufacturer's instructions for concentration and contact time. The instruments should be transported to the reprocessing site in the disinfection container for burs.

Cleaning and disinfection:
According to the recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) and the Robert Koch Institute (RKI) , further reprocessing is preferably performed automated and disinfection is preferably performed thermally.

Validated automated reprocessing

Equipment used:

Manual pre-cleaning for automatic cleaning/disinfection: Ultrasonic bath with neodisher Septo PreClean 0.5 - 1% washer-disinfector (WD) Miele G7835; programme: Vario TD; cleaning agent: neodisher® Mediclean Dental, 0.2 - 1% at 50 - 60°C; Instrument rack for rotating instruments (e.g. Edenta Ref. 40600 - 40603).

Reprocessing:

1. Remove instruments from the disinfection container for burs or interim rack for manual PRE-CLEANING immediately before machine reprocessing.
2. Pre-cleaning:
   a. Remove visible contamination or coarse soiling from the surface of the instrument using a hard plastic brush (not a steel brush) under cold running water (<40°C, drinking water quality).
   b. Place the instruments in a suitable instrument rack/sieve and clean them in an ultrasonic bath filled with cleaning agent and disinfectant (e.g. neodisher® Septo PreClean, 0.5 - 1%, room temperature) for 15 minutes (instruments must be completely covered by the cleaning solution). Ensure that all instruments or their parts are fully exposed to the cleaning agent. The ultrasonic cleaning solution must be replaced before each use.
3. Rinse instruments under cold running tap water (drinking water quality < 20°C) for 10 seconds to ensure that no residues of the cleaning agent/disinfectant get into the machine (WD).
4. Instruments must not touch each other during cleaning, so place them in a suitable instrument rack.
5. Place or position the instrument rack in the washer-disinfector so that the spray jet hits the instruments directly.
6. Add cleaning agent to the washer-disinfector (e.g. neodisher® Mediclean Dental - 0.2 - 1% - 50 - 60°C) according to the instructions on the product label and the washer-disinfector manufacturer's instructions.
7. Start the Vario TD programme for thermal disinfection, for programme sequence see Vario TD programme sequence. Thermal disinfection is performed in accordance with national regulations and the A_0 value (EN/ISO 15883).
8. To prevent staining, we recommend using fully demineralised water in the rinse phase.
9. Remove instruments from the washer-disinfector at the end of the programme and dry them - preferably with clean, dry compressed air in accordance with RKI recommendations.
10. Visual inspection for cleanliness and intactness (e.g. with a watchmaker's loupe, etc. with 8x to 10x magnification). Sort out faulty instruments (missing diamond coating, blunt/broken cutting edges, fractured working parts, corroded surfaces, bent instruments, etc.). If residual contamination is present, repeat cleaning and disinfection until contamination is no longer visible. If contamination is still visible after repeated cleaning and disinfection, the instruments must be disposed of.

The following cleaning and disinfection procedure in accordance with DIN EN ISO 17664 and DIN EN ISO 15883 has been validated and approved.

Process parameters programme VarioTD:	
Pre-cleaning	3 min with cold tap water, drinking water quality <20°C
Emptying	
Cleaning	10 min. at 50 - 60°C, 0.2 - 1% neodisher® Mediclean Dental with demineralised water. Dosage according to manufacturer's instructions
Emptying	
Rinsing	1 min. with demineralised water (40 - 45°C)
Emptying	
Rinsing	1 min. with demineralised water (< 20°C)
Emptying	
Thermal disinfection	5 min. at 90 - 92°C (A_0value 3000) and demineralised water
Emptying	
Automatic hot air drying	20 30 min. at > 60°C (in the rinsing compartment)

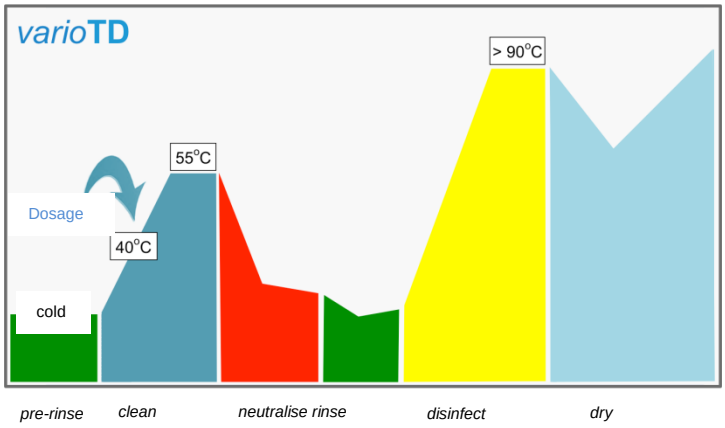

Fig. 1 - Schematic programme sequence of the VarioTD programme

Standardised manual reprocessing (alternative, not recommended)

Equipment used:

Plastic brush / suitable cleaning agent and disinfectant (e.g. neodisher Septo PreClean) with disinfection certificate for rotary instruments / ultrasonic device / cleaning solution

Reprocessing:

1. Remove instruments from the disinfection container for burs or interim rack immediately before manual reprocessing.
2. Pre-cleaning (not for polishers and ceramic abrasives):
   a. Remove visible contamination or coarse soiling from the surface of the instrument using a hard plastic brush (not a steel brush) under cold running water (<40°C, drinking water quality).
   b. Place the instruments in a suitable instrument rack/sieve and clean them in an ultrasonic bath filled with cleaning agent and disinfectant (e.g. neodisher® Septo PreClean, 0.5 - 1%, room temperature) for 15 minutes (instruments must be completely covered by the cleaning solution). Ensure that all instruments or their parts are fully exposed to the cleaning agent. The ultrasonic cleaning solution must be replaced before each use.
3. Instruments must not touch each other during cleaning, therefore place them in a suitable instrument rack in the ultrasonic device filled with cleaning agent and disinfectant (instruments must be completely covered by the cleaning solution). Ensure that all instruments or their parts are fully exposed to the cleaning agent. The ultrasonic cleaning solution must be replaced before each use.
4. As the vibrations in the ultrasonic bath can be absorbed by the materials of the polishers and ceramic abrasives, these should only be reprocessed in the cleaning solution.
5. For cleaning and chemical disinfection in the ultrasonic device (min. 35 khz), observe the manufacturer's instructions for the cleaning/disinfectant agent regarding concentration and exposure time (e.g. neodisher Septo PreClean 0.5 - 1%, temperature 20 - 25°C - 15 min.). The exposure time only begins when the last instrument has been placed in the ultrasonic device and must not be less than this time. Clean and disinfect at max. 45°C (risk of protein coagulation).
6. After the exposure time has elapsed, thoroughly rinse off any disinfectant residue on the instruments with clean running water (the use of fully demineralised water in the rinse phase prevents staining).
7. Dry instruments - according to RKI recommendation (preferably with clean, dry compressed air)
8. Visual inspection for cleanliness and intactness (e.g. with a watchmaker's loupe, etc. with 8x to 10x magnification). Sort out faulty instruments (missing diamond coating, blunt/broken cutting edges, fractured working parts, corroded surfaces, bent instruments, etc.). If residual contamination is present, repeat cleaning and chemical disinfection until no more contamination is visible. If contamination is still visible after repeated cleaning and disinfection, the instruments must be disposed of.

Steam sterilisation:
Critical B instruments must always be subsequently sterilised in a steam steriliser!!!

Steam sterilisation in a fractionated vacuum process with a validated process
(device according to EN 13060, Class B)

- Packaging suitable for the instrument and sterilisation procedure (see DIN 58952/53 or EN 868) must be selected; it must be large enough to ensure that the seal is not under tension.
- Fractionated pre-vacuum (4-fold).
- 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 ingredients. The recommended limit values (see table Fig. 2) for the ingredients of feed water and steam condensate are defined in DIN EN 13060. When sterilising several instruments, the maximum load of the steam steriliser must not be exceeded. The device manufacturer's specifications must be observed.

Documented release after successful sterilisation.

Transport and storage:
Transport and storage must be clean, protected from dust, moisture and recontamination and in compliance with the storage periods applicable in your country. The instruments must always be protected from chemicals, acids, heat and extreme temperature fluctuations.

Material resistance:
When selecting cleaning agents and disinfectants, please ensure that they do not contain the following components: - organic, mineral and oxidising acids / - strong alkalis (pH > 10.5 not permitted, only neutral or slightly alkaline cleaning agents recommended) / - do not use alkaline cleaning agents for polishers / - alcohols, ethers and ketones, benzines / - oxidising agents. Never clean all instruments and sterilisation trays with metal brushes or steel wool.

The manufacturer has ensured that the reprocessing procedures listed above are suitable for reprocessing the named instrument group for reuse. The reprocessor is responsible for ensuring that the reprocessing actually performed with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This normally requires routine checks of the validated automated or standardised manual reprocessing procedures. Likewise, any deviation from the procedures listed here (e.g. use of other process chemicals) should be carefully evaluated by the reprocessor for effectiveness and possible adverse consequences.

Observe the legal regulations applicable in your country for the reprocessing of medical devices (e.g. www.swissmedic.ch)

Fig. 2 - Impurities in the condensate and feed water

	Feed water	Condensate
Evaporation 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
Traces of heavy metals other than 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 value	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 has formed from steam coming from the empty sterilisation chamber.		