



Manufacturer's Information

on the reprocessing
of instruments according
to DIN EN 17664

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Medical Devices Critical A and B

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Products:

The present Manufacturer's Information sheet applies to all instruments supplied by Drendel + Zweiling that are used for surgical, periodontal or endodontic treatments.

They can be applied to both reusable and single-use instruments. These include rotary tungsten carbide and diamond instruments as well as instruments made of stainless steel.

Instruments delivered in a non-sterile condition have to be prepared before use, even if they are intended for single use.

Limited number of reprocessing cycles:

Disposable products (marked ② on the packaging) must not be reprocessed. The reuse of these disposable products poses a risk of infection and/or the devices are no longer safe to use. A safe, risk-free reuse can therefore not be guaranteed.

The end of a product's service life always depends on the degree of damage and wear incurred during use. Do not exceed the permitted frequency of reuse if this is known.

- Work station:** The hygiene regulations valid in the country of use have to be observed.
- Storage and transport:** Place instruments in a cleaning/disinfection tank filled with a suitable detergent/disinfectant (e.g. DC Evo, validated at 2%, Komet Dental/Alpro Medical, alkaline, aldehyde-free) immediately after use in the mouth. The immersion of the instruments prevents the drying of residues (protein fixation) and facilitates the cleaning of the instruments. It is recommended to process the instruments within one hour of use at the very latest.
- The instruments should be in the cleaning/ disinfection tank when transported to the site where the reprocessing is to take place.
- Cleaning and disinfection:** The further reprocessing should preferably be carried out mechanically. (This is obligatory for the reprocessing of critical B instruments.)

Validated mechanical reprocessing

Equipment used:

- Washer/disinfector as per EN ISO 15883 (co. Miele, with Vario TD-program or co. Melag with universal program)
- Suitable detergent (Neodisher Medi-Clean Forte; co. Dr. Weigert)
- Instrument block for rotary instruments
- Nylon brush or interdental brush

Reprocessing:

1. Remove instruments from cleaning/ disinfection tank or interim support immediately before mechanical reprocessing and rinse instruments thoroughly under running water to prevent any residues of the detergent/disinfectant from getting into the machine. Completely remove any stubborn contamination with the nylon brush under water level, constantly turning the instrument.
2. Place the instruments in a suitable bur block.
3. Place the bur block in the washer/disinfector in such a way that the instruments are directly hit by the spray jet.
4. Put detergent into the washer/disinfector, following the indications on the label and the instructions of the manufacturer of the washer/disinfector.
5. Start the Vario TD program or universal program (for diagram of program sequence see fig. 2) including thermal disinfection. Thermal disinfection takes place allowing for the Ao value and observing national provisions (EN/ISO 15883).
6. On completion of the cycle remove instruments from the washer/disinfector and dry (preferably with compressed air). When drying the bur block make sure that even hard-to-reach areas are dried properly.
7. Visual inspection with a suitable magnifier (experience has shown that a visual inspection can take place under 8x magnification) to ensure that the instrument is clean and undamaged. If after mechanical reprocessing there are still visible residues of contamination, repeat the cleaning and disinfecting process until no visible contamination is left.



Fig. 1 Correct position of the bur block in the washer/disinfector.

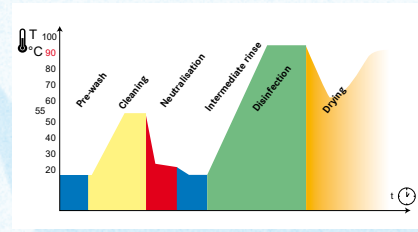


Fig. 2 Diagram of the program sequence of the Vario TD programme.

Standardized manual reprocessing (alternative, for critical A)

Equipment used:

- Nylon brush
- Suitable detergent/disinfectant for rotary instruments with proven disinfecting effect (e.g. DC Evo, validated at 2%, Komet Dental/Alpro Medical, alkaline, aldehyde-free, alcohol-free).
- Ultrasonic device (alternatively: instrument bath)

Reprocessing:

1. Remove instrument from cleaning/disinfection tank or from the interim support and thoroughly rinse off surface contamination under running water. Completely remove any stubborn contamination with the nylon brush under water level, constantly turning the instrument.
2. Place the instruments in a suitable sieve or instrument block into the ultrasonic device filled with detergent/disinfectant.
3. During chemical cleaning/chemical disinfection in the ultrasonic device, observe the instructions of the manufacturer regarding concentration and immersion time. Be sure to observe the full correct immersion time which does not start until the last instrument has been placed into the ultrasonic device. Attention: do not exceed 45°C (risk of protein coagulation)!
4. On completion of the immersion time, rinse instruments at least 5 times for one minute each time with suitable water (preferably with demineralized water to avoid residues of lime), or alternatively with town water.
5. Dry instruments (preferably with medical compressed air).
6. Visual inspection to ensure that the instrument is clean and undamaged. If there are still visible residues of contamination, repeat the cleaning and chemical disinfecting process until no visible contamination is left.

Control and functional test: Instruments showing the following defects are to be discarded immediately:

- Missing diamond coating (uncoated areas)
- Blunt and chipped blades
- Deformations (e.g. bent/twisted/fractured instruments)
- Corroded surfaces

Packaging: Make sure that the packaging is suitable for the instrument and the chosen method of sterilisation in compliance with EN ISO 11607. Single pack: The packaging must be large enough to ensure that the seal is not under tension. In the set: Place instruments onto the tray provided or onto universal sterilisation trays. The instruments must be protected. Use an appropriate method to pack the tray. Instrument with a limited number of reuses are to be marked accordingly.

Sterilisation: Steam sterilisation using a vacuum process at 134°C in a device that complies with DIN EN 13060 and whose effectiveness is in accordance with EN ISO 17665; validated processes.

- Fractionated pre-vacuum (type B)
- Sterilisation temperature: 134°C
- Hold time: at least 5 minutes (full cycle)
- Drying time: at least 10 minutes

In order to prevent staining and corrosion, the steam must be free of particles. Make sure not to exceed the maximum capacity of the sterilizer when sterilizing several instruments. Follow the instructions of the device manufacturer.

Transport and storage: The packed sterile goods must be transported and stored in a clean environment, protected from dust, moisture and sources of recontamination.

Universally valid notes: The decisive factors to ensure efficient reprocessing are the thorough cleaning of the instruments and the compatibility of the detergent and disinfectant used with the materials to be processed.

Observe the legal provisions regarding the reprocessing of medical products valid in your country. The manufacturer confirms that the above detailed reprocessing methods are suitable for preparing the abovenamed instrument group to enable their reuse. The user of the medical device is responsible for ensuring that the applied method is carried out with appropriate equipment, materials and trained personnel at the reprocessing site and that it actually achieves the desired result. To guarantee this, routine controls of the validated mechanical and/or standardized manual preparation methods are normally necessary. Any deviation from the above detailed process (e.g. use of different chemicals) must be carefully checked by the operator to ensure effectiveness and to avoid possible adverse consequences.