



Manufacturer's Information

on the reprocessing
of re-sterilisable instruments
according to DIN EN 17664

As at: 05/17

Revision: 3

Medical products Critical A and B

Manufacturer:

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Products:

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

These include rotary tungsten carbide and diamond instruments as well as stainless steel instruments.

Instruments delivered in a non-sterile condition have to be prepared prior to first 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. A safe, risk-free reuse can therefore not be guaranteed.

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

Frequent reprocessing does not affect the performance of these instruments.

Work station:	Hygienic precautions according to the provisions valid in your country.
Storage and transport:	Place instruments in a cleaning/disinfection tank (Fräsator) filled with a suitable detergent/disinfectant (e.g. Komet® DC1®/alkaline, aldehyde-free) immediately after use in the mouth to prevent drying of residues on the instruments (protein fixation). 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 (Fräsator) when transported to the site where the reprocessing is to take place.
Cleaning and disinfection:	The further reprocessing should be carried out mechanically (according to the recommendations of the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute).

Validated mechanical reprocessing

Equipment used:

- Cleaning/disinfection device (co. Miele, with Vario TD-programme)
1.5g/l Komet DCTherm®, REF 9869/mildly alkaline
- Bur block for rotary instruments

Reprocessing:

1. Remove instruments from cleaning /disinfection tank (Fräsator) 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.
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 powder 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 programme (for diagram of program sequence see **fig. 1**) including thermal disinfection. Thermal disinfection takes place allowing for the A₀ value and observing national provisions (prEN/ISO 15883).
6. On completion of the cycle remove instruments from the washer/disinfector and dry (preferably with compressed air as recommended by the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute). When drying the bur block please make sure that even hard-to-reach areas are dried properly.
7. Visual examination with a suitable magnifying device 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.

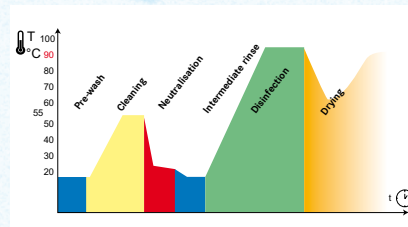


FIG. 1 Diagram of the program sequence of the Vario TD programme

Standardised manual reprocessing (alternative)

Equipment used:

- Nylon brush (e.g. Drendel+Zweiling ref. P9645)
- Suitable detergent/disinfectant for rotary instruments with proven disinfecting effect (e.g. Komet DC1, ref. 9826/alkaline, aldehyde-free, DGHM/VAH approved).
- Ultrasonic bath (alternatively: instrument bath)

Reprocessing:

1. Remove instrument from cleaning/disinfection tank (Fräsator) or from the interim support and rinse off surface contamination under running water. Remove stubborn contamination with a nylon brush under running water, turning the instrument constantly.
2. Place the instruments in a suitable sieve or bur block into the ultrasonic device filled with detergent/disinfectant.
3. During chemical cleaning/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 thoroughly with suitable water (preferably with demineralised water to avoid residues of lime).
5. Dry instruments (preferably with compressed air as recommended by the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute).
6. Visual examination with a suitable magnifying device 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

Packing:

Make sure that the packaging is suitable for the instrument and the chosen method of sterilisation. Single pack: The packaging must be large enough to ensure that there is no pressure on the seal.

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 limited use are to be marked accordingly.

Sterilisation:

Steam sterilisation using a vacuum process at 134°C in a device that complies with the provisions of DIN EN 13060; with validated processes.

- Fractionated pre-vacuum (type B) or simplified pre-vacuum (type S)
- 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 protected from dust, moisture and recontamination during transport and storage.

Universally valid notes:

Observe the legal provisions regarding the reprocessing of medical products valid in your country (e.g. www.rki.de).

The manufacturer confirms that the above detailed reprocessing methods are suitable for preparing the above named instrument group to enable their reuse. The person carrying out the reprocessing 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 manual preparation methods are 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.