Manufacturer's Information

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

As at: 05/16

Revision: 2

Medical devices Semi-critical A + B

Manufacturer:

Drendel+Zweiling
DIAMANT GmbH
Schürenbreder Weg 27
32689 Kalletal · Germany

fon: +49 (0) 5264 6579280
fax: +49 (0) 5264 6579284
info@drendel.com
www.drendel.com

Products:

The present manufacturer's information applies to all instruments supplied by Drendel + Zweiling that are used for the following non-invasive:

- preventive
- restoring
- prosthetic
- orthodontic treatments

These include polishers, ceramic abrasives, rotary tungsten carbide and diamond instruments for the preparation of cavities and crowns, for removing and retouching fillings and for the separation of crowns as well as rotary diamond discs for interproximal enamel reduction as well as finishing and separating strips.

Instruments delivered in a non-sterile condition have to be prepared prior to first use. The reuse of disposable articles (marked ② on the packaging) is not permitted (e.g. laminated polishers and dental brushes). The reuse of disposable products poses a risk of infection. A safe, risk-free reuse can therefore not be guaranteed.

Limited number of reprocessing cycles:

The end of a product's service life depends on its degree of damage and wear. 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 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) and to facilitate the cleaning of the instruments. It is recommended to reprocess 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 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:

- Washer/disinfector (co. Miele, with Vario TD-programme)
- 1.5g/l Komet DCTherm, 9869/mildly alkaline
- Bur block

Reprocessing:

1. Remove instruments from cleaning /disinfection tank (Fräsator) immediately before mechanical reprocessing and rinse 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 A_0 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 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.
8. Attention! In the case of mechanical cleaning only (i.e. without proven disinfection), it is essential to submit the unwrapped instruments to a final thermal disinfection cycle in the steam sterilizer in suitable supports or sieves.

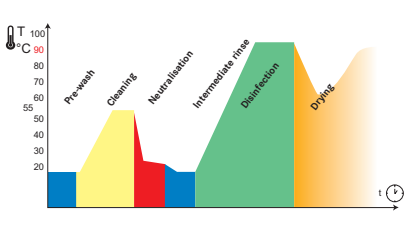

FIG. 1 Diagram of the program sequence of the Vario TD programme

Standardised manual reprocessing (alternative)

Equipment used:

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

Reprocessing:

1. Remove instrument from cleaning/disinfection tank. Rinse off surface contamination under running water. Remove stubborn contamination with a nylon brush, turning the instrument constantly, and rinse instrument thoroughly with running water.
2. Place the instruments in a suitable sieve or bur block into the ultrasonic device filled with detergent/disinfectant. Attention! Reprocess polishers in the instrument bath – the vibrations in the ultrasonic bath might be absorbed by the elastic materials of the polishers. Reprocess polishers with suitable, alcohol-free agents (e.g. Komet DC1).
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.
7. Final thermal disinfection of the unwrapped instruments in suitable supports or sieves.

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 instruments)
- Corroded surfaces

Transport and storage:

The sterile packed 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 reprocessing the above named 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 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.