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).

Medical products
Semi-critical A and B

Manufacturer:
Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25 · 32657 Lemgo
Tel. +49 (0) 5261 701-0
Fax +49 (0) 5261 701-289
info@brasseler.de
www.brasseler.de

Products:
The present manufacturer’s information applies to all instruments supplied by Gebr. Brasseler that are used for the following non-invasive:
• preventive
• restoring
• prosthetic
• orthodontic treatments. These include polishers, ceramic abrasives, rotary ceramic, tungsten carbide and diamond instruments for the preparation of cavities and crown stumps, for removing and retouching fillings and for the separation of crowns and rotary and oscillating diamond discs for interproximal enamel reduction as well as finishing and separating strips. Instruments made of tool steel (round burs 1, finishers 41, 48, dental plaque removers 9119 and 9120) are neither suitable for the washer/disinfector nor for steam sterilisation. A suitable tungsten carbide instrument should therefore be used instead. Please also follow the instructions of the Manufacturer’s Information on sonic and ultrasonic tips. 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 (Fräsator) filled with a suitable detergent/disinfectant (e.g. Komet® DC1®/alkaline, aldehyde-free) (fig. 1) 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 (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:**
- Washer/disinfector (co. Miele, with Vario TD-programme)
- 1.5 g/l Komet DCTherm®, 9869/mildly alkaline (DCTherm is only available in Germany)
- Komet bur block, 9933L3

**Manual pre-cleaning:**
- 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.
- Place the instruments in a suitable bur block.
- Place the bur block in the washer/disinfector in such a way that the instruments are directly hit by the spray jet (fig. 2)
- Put detergent powder into the washer/disinfector, following the indications on the label and the instructions of the manufacturer of the washer/disinfector.
- Start the Vario TD programme (for diagram of program sequence see fig. 3) including thermal disinfection. Thermal disinfection takes place allowing for the $A_0$ value and observing national provisions (prEN/ISO 15883).

**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 (see fig. 4 and 5).

- 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.
- Attention! In the case of mechanical cleaning only (i.e. without proven disinfection) it is essential to finish with a final thermal disinfection of the unwrapped instruments in the steam sterilizer in suitable supports or sieves.
Standardised manual reprocessing (alternative)

**Equipment used:**
- Nylon brush (e.g. Komet 9873)
- Suitable detergent/disinfectant for rotary instruments with proven disinfecting effect (e.g. Komet DC1, 9826/alkaline, aldehyde-free, DGHM approved).
- Ultrasonic bath (alternatively: instrument bath)

**Reprocessing:**
- Remove instrument from cleaning/disinfection tank (Fräsator). Rinse off surface contamination under running water (fig. 6). Remove stubborn contamination with a nylon brush, turning the instrument constantly, and rinse instrument thoroughly with running water.
- Place the instruments in a suitable sieve or bur block into the ultrasonic device filled with detergent/disinfectant (fig. 7 and 8). 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 and Arkansas stones with suitable, alcohol-free agents (e.g. Komet DC1).
- 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]!
- On completion of the immersion time, rinse instruments thoroughly with suitable water (preferably with demineralised water to avoid residues of lime).
- Dry instruments (preferably with compressed air as recommended by the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute) (fig. 9).
- 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 (fig. 10).
- Final thermal disinfection of the unwrapped instruments in suitable supports or sieves (fig. 11).
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:
The decisive factors to ensure efficient reprocessing are the thorough cleaning of the instruments and the material compatibility of the detergent and disinfectant used. Fully virucidal agents cannot meet all of these criteria at the same time, which is why Komet DC1 is only virucidal to a limited extent. The full virucidal effect during reprocessing is obtained by the final thermal treatment in the autoclave. This is in compliance with the recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention of the RKI stating that thermal disinfection is the preferred method. 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 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.