Manufacturer's Information
on the reprocessing of instruments
according to DIN EN 17664

Medical Devices Semi-critical A and B

As at: 07/23
Revision: 4

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Products:
The present Manufacturer's Information sheet applies to all instruments supplied by Gebr. Brasseler that are used for the below listed, non-invasive therapies:

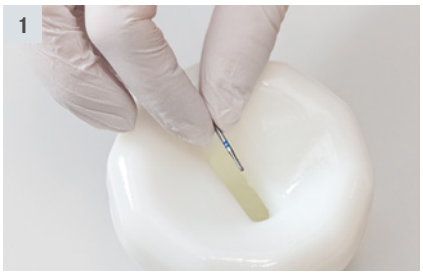
- preventive
- restorative
- dental prosthetic
- orthodontic treatments

The information can be applied to both reusable and single-use instruments. These include polishers, ceramic abrasives, rotary ceramic, tungsten carbide and diamond instruments that are used for the preparation of cavities and crowns and for the removal of and work on fillings and for the separation of crowns, rotary and oscillating diamond discs for enamel reduction as well as finishing and separating strips. Instruments made of tool steel (round bur 1, finishers 41 and 48, tartar removers 9119 and 9120) are neither suited for washers/disinfectors nor for steam sterilizers. The user should switch to a suitable tungsten carbide instrument. Please also observe the Manufacturer's Information sheets for sonic and ultrasonic tips. Instruments delivered in a non-sterile condition have to be processed prior to first use. Dental brushes have to be reprocessed mechanically.

Limited number of reprocessing cycles:
Disposable products (marked ② on the packaging) must not be reprocessed (e.g. polishers with lamellae and dental brushes). 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.

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) (fig. 1) 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.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Cleaning and disinfection:
The further reprocessing should preferably be carried out mechanically.

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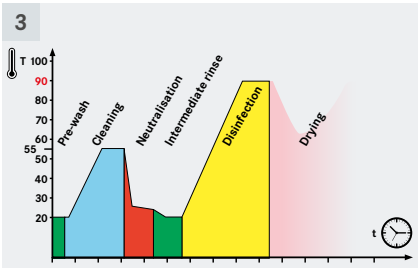

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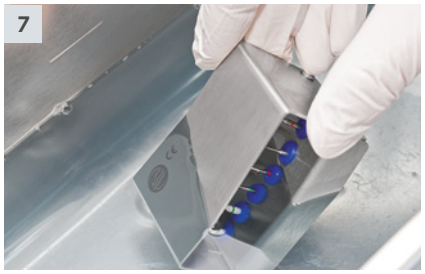
Validated mechanical reprocessing

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 Komet, ref. 9933L3
- Nylon brush (e.g. Komet 9873)

Reprocessing:

- Remove instruments from the cleaning /disinfection tank immediately before mechanical reprocessing and rinse thoroughly under running water to ensure that no residues of the detergent/disinfectant get into the machine. Completely remove any stubborn contamination with the nylon brush under water level, constantly turning the instrument.
- 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 into the washer/disinfector, following the indications on the label and the instructions of the manufacturer of the washer/disinfector.
- Start the Vario TD program or universal program (for diagram of program sequence (see fig. 3) including thermal disinfection. Thermal disinfection takes place in the washer/disinfector (at least 5 minutes at 90°C or A_0 value ≥ 3000).
- On completion of the cycle remove instruments from the washer/disinfector and dry (fig. 8) (preferably with compressed air). When drying the bur block make sure that even hard-to-reach areas are dried properly (fig. 4 and 5).
- Visual inspection 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 case of mechanical cleaning only (without verifiable disinfection), this has to be followed by a final thermal disinfection in a steam sterilizer, unwrapped in suitable supports or sieves.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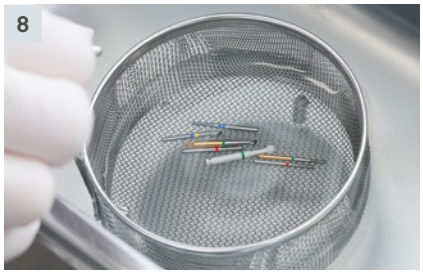
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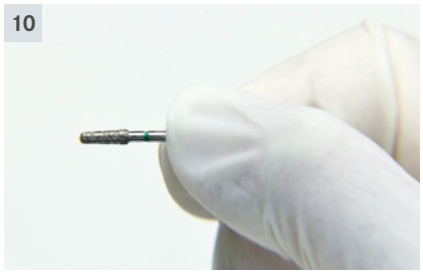
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Standardized manual reprocessing (alternative)

Equipment used:

- Nylon brush (e.g. KOMET ref. 9873)
- Suitable detergent/disinfectant for rotary instruments with proven disinfecting effect (e.g. DC Evo, validated at 2%, Komet Dental/Alpro Medical, alkaline, aldehyde-free).
- Ultrasonic device (alternatively: instrument bath)

Reprocessing:

- Remove instrument from cleaning/disinfection tank and thoroughly rinse off surface contamination under running water (fig. 6). Completely remove and rinse off any stubborn contamination with the nylon brush under water level, constantly turning the instrument.
- Place the instruments in a suitable sieve or instrument block into the ultrasonic device filled with detergent/disinfectant (fig. 7 and 8).
  Attention! Reprocess polishers in the instrument bath as the vibrations in the ultrasonic bath could be absorbed by the elastic materials. Prepare polishers and Arkansas stones only with suitable, alcohol-free agents (e.g. DC Evo, validated at 2%, Komet Dental/ Alpro Medical alkaline, aldehyde-free).
- During chemical cleaning and 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)!
- On completion of the immersion time, rinse instruments thoroughly with suitable water (preferably with demineralized water to avoid residues of lime).
- Dry instruments (preferably with medical compressed air) (fig. 9).
- 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 (fig. 10).
- Final thermal disinfection in a steam sterilizer according to EN ISO 13060 or EN 285, unwrapped and 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 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 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 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.

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