

Manufacturer's Information

on the reprocessing of instruments
according to DIN EN 17664



Sonic and ultrasonic tips

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Manufacturer:

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Products:

The present manufacturer's information applies to all sonic and ultrasonic tips as well as cooling adapters supplied by Gebr. Brasseler. Depending on the application, these are either in the risk group semi-critical B (e.g. tips for prophylaxis, work on fissures, work on interproximal surfaces, preparation of cavities, veneers and crown cores) or in the risk group critical B (e.g. tips for surgical, periodontal or endodontic treatments).

Important note:

The cleaning of sonic and ultrasonic tips and cooling adapters has to be carried out with the greatest care. Sonic and ultrasonic tips and cooling adapters delivered in a non-sterile condition have to be prepared prior to first use.

Limited number of reprocessing cycles:

The end of a product's service life 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 sonic and ultrasonic tips and cooling adapters 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 prevents drying of residues on the instruments (protein fixation). Hold sonic and ultrasonic tips and cooling adapters at an angle when placing them into the liquid to ensure that the liquid reaches all hollow spaces. 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.



Validated mechanical reprocessing

Equipment used:

- Washer/disinfector according to ISO 15883 (co. Miele, with Vario TD-program or co. Melag with universal program)
- Suitable detergent (Neodisher Medi-Clean Forte, Dr. Weigert)
- Rinse adapter for sonic tips (Komet ref. SF1978) and rinse adapter for cooling adapter and ultrasonic tips (Komet ref. SF1977)
- Tip changer (Komet ref. SF1975) and nozzle cleaner (accessories supplied with the sonic hand pieces for sonic tips) or tip changer for ultrasonic tips
- Cleaning wire 97509 for sonic and ultrasonic tips
- 10 ml syringe + cannula
- Nylon brush (e.g. Komet ref. 9873)

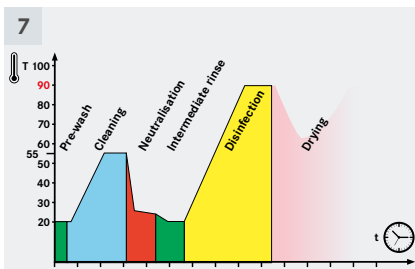
Pre-cleaning:

- Remove sonic tip or sonic tip with cooling adapter or ultrasonic tip from cleaning /disinfection tank immediately before mechanical reprocessing.
- Always separate the sonic tip and the cooling adapter with a tip changer before starting the cleaning cycle, to ensure proper reprocessing of both products (observe directions in the instructions for use provided with the sonic tips). Remove stubborn contamination with a nylon brush under running water, turning the sonic or ultrasonic tip/cooling adapter constantly.

- Check patency of the cooling passage by guiding the cleaning wire or nozzle cleaner through the passage. Replace sonic or ultrasonic tip if the passage is obstructed.

Reprocessing:

- Rinse sonic or ultrasonic tip and cooling adapter thoroughly under running water to prevent any residues of the detergent/disinfectant from getting into the washer/disinfector (fig. 2 and 3).
- Unscrew the nozzle on the injector bar of the washer/disinfector. Then screw or stick the external thread of the rinse adapter SF1978 (fig. 4) in the silicon holders on the injector bar. Clean and disinfect the rinsing adapter regularly, as described in the reprocessing recommendations for sonic and ultrasonic tips. Now screw the sonic tip in the internal thread at the top of the rinse adapter (fig. 4). If the cooling adapter SF1979 (fig. 5) or an ultrasonic tip (fig. 6) is used, proceed as follows: Once the nozzle on the injector bar of the washer/disinfector has been unscrewed, screw or stick the large external thread of the rinse adapter SF1977 in the silicon holders of the injector bar. Now screw the cooling adapter or ultrasonic tip in the external thread at the top of the rinse adapter (fig. 5 and 6). Please observe the directions in the respective instructions for use.
- Put chemical 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. 7) including thermal disinfection. Thermal disinfection takes place allowing for the A0 value and observing national provisions (EN/ISO 15883).
- On completion of the cycle remove sonic or ultrasonic tip and cooling adapter from the washer/disinfector and dry (preferably with low-germ, oil-free compressed air). When drying the inside of the instruments, please make sure to hold the compressed air gun close to the cooling passage, in order to guarantee that sufficient air flows through the sonic or ultrasonic tip and cooling adapter.
- 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.



Standardized manual reprocessing (alternative for semi-critical B)

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).
- Tip changer (Komet ref. SF1975) and nozzle cleaner (accessories supplied with the sonic hand pieces) or tip changer for ultrasonic tips
- Cleaning wire 97509 for sonic and ultrasonic tips
- 10 ml syringe + cannula
- Sterilisation container for sonic and ultrasonic tips and cooling adapters (Komet ref. 9952)
- Ultrasonic bath or instrument bath

Pre-cleaning:

- Remove sonic or ultrasonic tip and cooling adapter from cleaning /disinfection tank immediately before manual reprocessing.
- Always separate the sonic or ultrasonic tip and the cooling adapter with a tip changer before starting the cleaning cycle, to ensure proper reprocessing of both products (observe directions in the instructions for use provided with the sonic tips).
- Check patency of the cooling passage by guiding the cleaning wire or nozzle cleaner through the passage. Replace sonic or ultrasonic tip if the passage is obstructed.

Reprocessing:

- Place sonic or ultrasonic tip/cooling adapter onto a 10ml syringe + cannula and rinse with detergent/disinfectant. In case of visible contamination emerging from the perforation, rinse again with detergent/disinfectant (fig. 8).
- In case of superficial contamination, rinse instrument under running water. Remove all stubborn contamination with a nylon brush under water level, turning the sonic or ultrasonic tip/cooling adapter constantly.
- Rinse sonic or ultrasonic tip/cooling adapter thoroughly with running water.
- Visual examination to ensure that the instrument is clean. If there are still visible residues of contamination, repeat the cleaning process until no visible contamination is left.
- Place sonic or ultrasonic tip/cooling adapter in a suitable container or support (e.g. Komet ref. 9952, fig. 9) into the ultrasonic device or instrument bath filled with detergent/disinfectant.
- During chemical disinfection in the ultrasonic device or instrument bath, observe the instructions of the manufacturer regarding concentration and immersion time. Please note that due to the inner bore holes, the chemical disinfection of sonic and ultrasonic tips in the ultrasonic bath always takes 10 minutes in a 2% solution. Be sure to observe the full correct immersion time which does not start until the last tip

has been immersed. Attention: do not exceed 45°C (risk of protein coagulation)!

- On completion of the immersion time, rinse sonic or ultrasonic tip/cooling adapter thoroughly with suitable water (preferably with demineralized water to avoid residues of lime or alternatively with town water). Rinse the perforation of the sonic or ultrasonic tip/cooling adapter with at least 10 ml of demineralized water by means of a syringe and cannula, to ensure that no residues of the detergent are left in the cooling passage.
- Dry sonic or ultrasonic tip/cooling adapter (preferably with sterile compressed air). When drying the inside of the instruments, please make sure to hold the compressed air gun close to the cooling passage, in order to guarantee that sufficient air flows through the sonic or ultrasonic tip or cooling adapter.
- Visual examination to ensure that the instrument is clean and undamaged. If there are still visible residues of contamination on the sonic or ultrasonic tip/cooling adapter, repeat the cleaning and chemical disinfecting process until no visible contamination is left.

**Control and function test:**

Sonic and ultrasonic instruments showing the following defects must not be reused and have to be discarded immediately:

- Blunt and chipped blades
- Missing diamond coating (uncoated areas)
- Deformations (e.g. bent sonic or ultrasonic tips)
- Corroded surfaces
- Sonic or ultrasonic tips with blocked cooling passage
- Defect thread

Packaging:**Sonic and ultrasonic tips of risk group semi-critical B:**

Both sonic and ultrasonic tips can be subjected to thermal disinfection in a steam sterilizer (fig. 10). To this end, sonic tips must be in an unwrapped condition inside a suitable container (e.g. ref. 9952), and ultrasonic tips should be in a torque wrench inside a suitable container (e.g. 97507).

Sonic and ultrasonic tips of risk group critical B:

Make sure that the packaging is suitable for the sonic and ultrasonic tips and their accessories. Single pack: The packaging must be large enough to ensure that the seal is not under tension. In a multi-pack: Place sonic or ultrasonic tips into a suitable sterilisation container as described above (e.g. ref. 9952 or 97507). For sterilisation, the container has to be sealed in suitable sterilization packaging (fig. 11).

Sterilisation:

Steam sterilisation using a vacuum process at 134 °C in a device that complies with effectiveness in compliance with DIN EN 13060; 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 in a clean environment 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. Observe the legal provisions regarding the reprocessing of medical products valid in your country.

The manufacturer warrants 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 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.