Manufacturer's Information
on the reprocessing of re-sterilisable instruments | according to EN 17664

Medical products
Trepan burs

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Products:
The present manufacturer's information applies to all surgical trepan burs supplied by Gebr. Brasseler and classified as risk group critical B.
Important note:
Instruments with internal passage and hollow spaces have to be cleaned with due diligence. 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.

Work station:
Hygienic precautions according to the provisions valid in your country.

Storage and transport:
Place instruments in a cleaning/disinfection tank (Fräsator) (fig. 1+2) 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 (Fräsator) when transported to the site where the reprocessing is to take place.


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Cleaning and disinfection:
The further reprocessing should be carried out mechanically.

Validated mechanical reprocessing

Equipment used:
- Washer/disinfector (co. Miele, with Vario TD-programme or co. Melag with universal programme)
- Suitable detergent (Neodisher Mediclean Forte; co. Dr. Weigert)
- Bur block for rotary instruments: Komet, e.g. 9933L3
- Nylon brush (e.g. Komet 9873) and round brush (e. g. interdental brush)

Manual pre-cleaning:
- Remove instruments from cleaning/disinfection tank (Fräsator) immediately before mechanical reprocessing. Remove dried residues with a nylon brush under running water, turning the instrument constantly (fig. 3). Pay special attention to the hollow spaces (fig. 4).
- Rinse instrument thoroughly under running water to prevent any residues of the detergent/disinfectant from getting into the machine.
- Visual examination with a suitable magnifying device to ensure that the instrument is clean (experience has shown that a magnification factor of 8 permits a visual examination). In case of residual contamination, repeat the cleaning process until no visible contamination is left.


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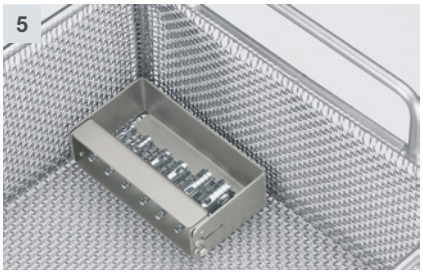
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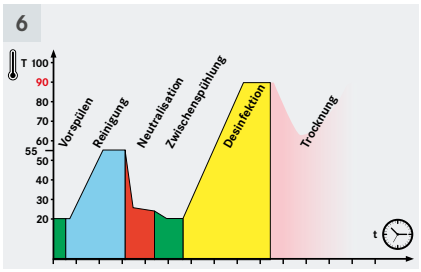


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Mechanical reprocessing:

- Place the instrument in a suitable bur block (fig. 5).
- Place the bur block in the washer/disinfector in such a way that the instruments are directly hit by the spray jet.
- 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, universal programme (for diagram of program sequence see fig. 6) 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). When drying the bur block please make sure that even hard-to-reach areas are dried properly.
- Visual examination to ensure that the instrument is clean and undamaged (fig. 7).
  If after mechanical reprocessing there are still visible residues of contamination, repeat the cleaning and disinfecting process until no visible contamination is left.

Control and functional test:

Instruments showing the following defects are to be discarded immediately:

- Blunt and chipped blades
- Deformations (e.g. bent 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 (fig. 8). The instruments must be protected. Use an appropriate method to pack the tray.

Sterilisation:

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