

Manufacturer's information

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

As at: 10/07

Revision: 0

Rotary instruments

Manufacturer:


KOMET MEDICAL
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Products:

The present manufacturer's information applies to all surgical instruments supplied by Gebr. Brasseler, i.e. rotary Tungsten carbide and diamond instruments as well as stainless steel instruments, with the exception of trepan burs.

Disposable products (marked  on the packaging) may not be reprocessed.
Instruments delivered in non-sterile condition have to be prepared prior to first use.

General information:

Please follow the recommendations and instructions provided by the manufacturer of the washer disinfector and the autoclave.

**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:

Immerse instruments in a suitable detergent/disinfectant (alkaline, aldehyde-free) immediately after use in the mouth to prevent residues from drying on the instruments (protein fixation). It is recommended to reprocess the instruments within one hour of use at the very latest.

Validated reprocessing procedure

Mechanical cleaning:**Equipment used:**

- Washer disinfectant (co. Miele, with Vario TD-programme*)
- deconex 28 ALKA ONE (co. Borer Zuchwil/alkaline)
- Bur block (e.g. KOMET MEDICAL, REF 9853M)

* Should the Miele washer disinfectant be unavailable, please observe the parameters of the Vario TD-program sequence (see fig. 1)

1. Immediately before mechanical reprocessing, rinse instruments thoroughly under running water to prevent any residues of detergent/disinfectant from getting into the machine.
2. Place the instruments in a suitable bur block.
3. Place the bur block in the washer disinfectant in such a way that the instruments are directly hit by the spray jet.
4. Start the Vario TD-programme (for diagram of program sequence see fig. 1) including thermal disinfection.

The cleaning procedure is carried out following the below pattern:

- 4 minutes' pre-wash with cold water
 - Emptying
 - 6 minutes' pre-wash with deconex 28 Alka One (co. Borer Zuchwil) at 55°C
 - Emptying
 - 3 minutes' neutralisation with warm tap water (>40°C)
 - Emptying
 - 2 minutes' intermediate rinse with warm tap water (>40°C)
 - Emptying
 - Thermal disinfection takes place allowing for the A₀ value and observing national provisions (prEN/ISO 15883)
5. Remove any residual moisture from the instruments with filtered compressed air, which does not lead to recontamination.

If after mechanical reprocessing there are still visible residues of contamination, repeat the cleaning and disinfecting process until no visible contamination is left. **The disinfectant deconex 28 ALKA ONE can be used for this, provided that the instructions on the label are observed.**

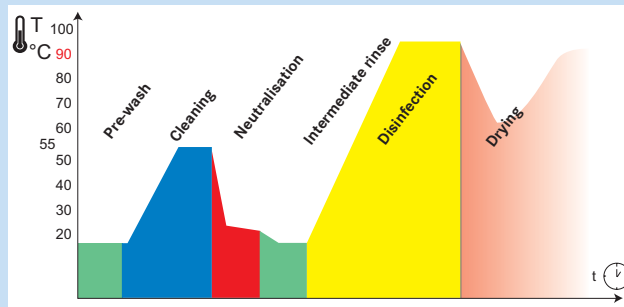


Fig.1 Diagram of the program sequence of Vario TD-programme

Control and functional test:

Instruments showing the following defects are to be discarded immediately:

- Missing diamond coating (blank spots)
- Blunt and chipped blades
- Bent instruments
- Corroded surfaces

Check the instruments visually for possible damage and wear. Blades should be even and free of nicks (the use of magnifying glasses is recommended).

Packing:

Single pack: Standardised packing material can be used. The bag must be large enough for the instrument to ensure that there is no pressure on the seal.
In the set: Place instruments onto the tray provided or onto universal sterilisation trays. 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 285; with validated processes.

1. Fractionated pre-vacuum (4 x)
2. Sterilisation temperature: 134°C
3. Hold time: 5 minutes (full cycle)
4. Drying time: 10 minutes

In order to prevent staining and corrosion, the steam must be free of particles. The recommended limits for particle contents in feed water and condensed steam are defined by standard EN 285.

Plasma sterilization: Sterilizer Sterrad 100S. Do not sterilize tungsten carbide instruments in the plasma sterilizer. The procedure is carried out according to a fixed pattern.

Make sure not to exceed the maximum capacity of the sterilizer when sterilizing several instruments (follow the instructions of the device manufacturer).

Storage:

The goods must be protected from dust, moisture and recontamination during 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 reprocessor is responsible for ensuring that the applied method is carried out with appropriate equipment and materials and by trained personnel at the reprocessing site and that it actually achieves the desired result.

To guarantee this, validations and routine controls of the process are necessary. Any deviation from the above detailed method (e.g. use of different chemicals) must be carefully checked by the operator to ensure effectiveness and to avoid possible adverse consequences.