



Manufacturer's information

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

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Rotary instruments for ENT surgery and neurosurgery

Manufacturer:

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Products:

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

Disposable instruments (marked  on the packaging) may not be reused. The reuse of these products poses a risk of infection and/or the safety of the products can no longer be guaranteed.

Instruments delivered in non-sterile condition have to be prepared prior to first use.

General instructions:

Please follow the recommendations and instructions provided by the manufacturer of the washer disinfectant 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 precaution according to the provisions valid in your country.

Storage and transport:

Immerse instruments in a suitable detergent/disinfectant (e.g. Komet®DC1® 9829/alkaline, aldehyde-free, and approved by the VAH) immediately after use on the patient 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.

Reprocessing procedure

Mechanical cleaning:**Equipment used:**

- Washer disinfector (co. Miele, with Vario TD-programme*)
- deconex 28 ALKA ONE (co. Borer Zuchwil/alkaline)
- Bur block (e.g. Komet Medical®, 9853M)

* Should the Miele washer disinfector be unavailable, please observe the parameters of the Vario TD-programme 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 disinfector in such a way that the instruments are directly hit by the spray jet.
4. Start the Vario TD-programme (for diagram of programme sequence see **fig. 1**) including thermal disinfection.
The cleaning procedure is carried out according to a fixed 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' neutralization 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, with 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.

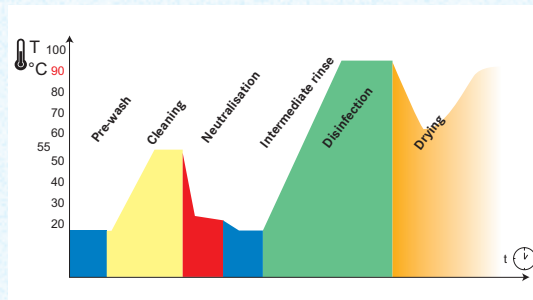


Fig. 1 Diagram of the program sequence of the Vario TD programme

Control and functional test:

Instruments showing the following defects are to be discarded immediately:

- Missing diamond coating (uncoated areas)
- Blunt and chipped blades
- Bent instruments
- Corroded surfaces

Check 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: Standardized packaging 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.

Sterilization:

Steam sterilization 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 (4x)
2. Sterilization 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 sterilisation: Sterilizer Sterrad 100S. Do not sterilized 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 instruction 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 preparing the above named instrument group to enable their reuse. The person carrying out the reprocessing 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.