

# Manufacturer's information

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



As at: 10/13  
Revision: 0


## Saw blades

### **Manufacturer:**

Komet Medical  
Gebr. Brasseler GmbH & Co. KG  
Trophagener Weg 25 · 32657 Lemgo

Tel.: +49 (0) 5261 701-400  
Fax: +49 (0) 5261 701-580  
info@kometmedical.de  
www.kometmedical.de

### **Products:**

The present manufacturer's information applies to all reusable saw blades supplied by Gebr. Brasseler.  
Disposable products (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 information:**

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.  
Do not exceed the permitted number of uses, if this is known.  
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 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.

## Validated reprocessing procedure

### Manual pre-cleaning:

Equipment: Plastic cleaning brush, Komet® DC1® (Komet Medical®, ref. no. 9829/alkaline, free of aldehyde, approved by the German Association for Hygiene and Microbiology (DGHM/VAH).

1. Immerse saw blades in Komet DC1 for at least 5 minutes.
2. Brush saw blades until no more visible contamination is left. In saw blades with structured surface (for example EZblades), not only the teeth but also the spaces on the surface of the blade should be brushed.
3. Rinse with cold tap water.

### Mechanical cleaning:

#### Equipment used:

- Washer disinfector (co. Miele, with Vario TD-programme\*)
- deconex 28 ALKA ONE (co. Borer Zuchwil/alkaline)

\* Should the Miele washer disinfector 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. 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 A<sub>0</sub> value and observing national provisions (prEN/ISO 15883)

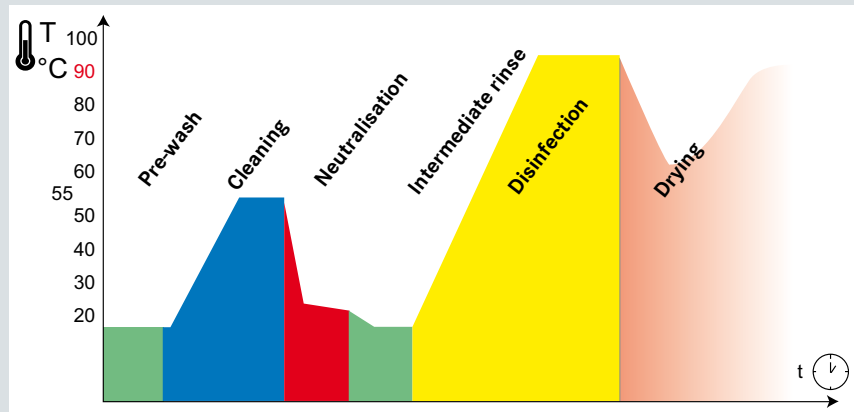


Fig.1 Diagram of the program sequence of Vario TD-programme

3. 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 left on the instrument, 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.

**Control and functional test:**

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.

**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 (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. 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 saw blades 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](http://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.

**Marking of modifications:**

Modified text passages that differ from the previous version are marked with a vertical line (|) at the page margin.