Manufacturer'sinformation

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

As at: 10/13
Revision: 0

GENIUS Shaver Blades

Manufacturer:

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Products:

The present manufacturer's information applies to all reusable GENIUS Shaver Blades supplied by Gebr. Brasseler.
Disposable products (marked ② 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:

Special care has to be taken when cleaning instruments with GENIUS Shaver Blades! Please follow the recommendations and instructions provided by the manufacturer of the washer disinfector and the autoclave.
Fading of the anodic coating of the GENIUS Shaver Blades does not constitute a reduction in quality.

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 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

Preparation for manual cleaning:

Demount GENIUS Shaver Blades.
If direct rinsing with the water gun is not possible, the GENIUSadapters have to be mounted to the Shaver Blades. This applies to all GENIUS Shaver Blades with lateral bur holes on the attachment. Assembly of the Komet Medical® GENIUSadapters is carried out according to the assembly instructions.

Manual pre-cleaning:

Equipment used:

- Komet® DC1®
  (Komet Medical 9829/alkaline, aldehyde-free, approved by the DGHM/VAH)
- Komet Medical GENIUSadapter (see fig. 1)
  Komet Medical GE9001.DY, GE9101.LI, GE9201.AC, GE9301.ST
- Water pistol, plastic cleaning brush

1. Thoroughly rinse off all contamination from the instrument's surface.
2. Rinse instrument groups under running tap water.
3. Clean the inner tubes of the instruments with a brush of matching diameter.
4. Rinse the blades and the trocar with a water pistol (cold tap water, 1.8 bars) directly or via the GENIUSadapter during approx. 20 seconds.

Preparation for mechanical cleaning:

Mount the Komet Medical GENIUSadapters (acc. to the assembly instructions).

Mechanical cleaning:

Equipment used:

- Washer disinfector (co. Miele, with Vario TD-programme*)
- deconex 28 ALKA ONE (co. Borer Zuchwil/alkaline)
- Komet Medical GENIUSadapter (see fig. 2)
  (Komet Medical GE9001.DY, GE9101.LI, GE9201.AC, GE9301.ST)

* Should the Miele washer disinfector be unavailable, please observe the parameters of the Vario TD-program sequence (see fig. 3)

Fig. 1 Example of GENIUSadapters

Fig. 2 Example of GENIUSadapter in washer disinfector

Mechanical cleaning:

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. 3) 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_0 value and observing national provisions (prEN/ISO 15883)
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, 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.**

Maintenance:

Apply a small amount of instrument lubricant oil to the inner tubes.

Control and functional test:

Reassemble GENIUS Shaver Blades and check for true running. Check instruments visually for damage and wear. The blades must be even and free from nicks (we recommend to use magnifying glasses, see check list for the Sterile Service Department for Komet Medical Shaver Blades).

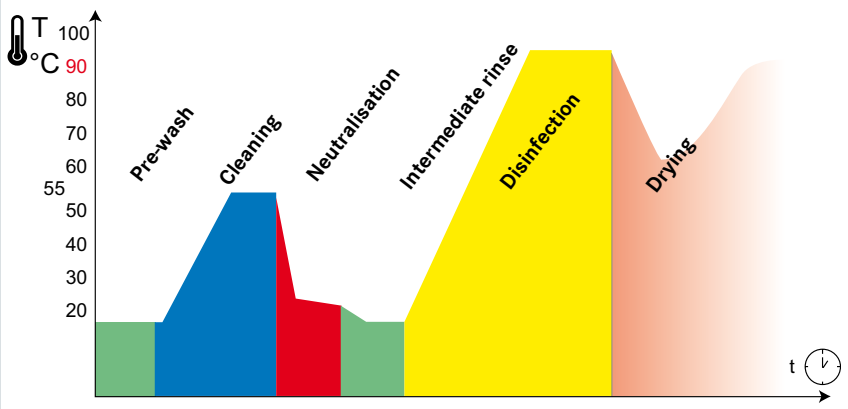

Fig.3 Diagram of the program sequence of Vario TD-programme

Packing:

Packing of instruments is carried out stripped down to their individual components.
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. 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.

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.

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.