DURAPLANT

Manufacturer information

for reprocessing
of resterilizable instruments
according to DIN EN ISO 17664

Medical Devices/Dental Instruments

Manufacturer:

Manufacturer
ZL Microdent-Attachment GmbH & Co. KG, v,
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Products:

This manufacturer's information applies to all dental instruments supplied by ZL Microdent-Attachment GmbH & Co. KG which are classified as surgical instruments in the risk group, critical B.
These are rotating titanium drills and guides, carbide instruments and instruments of hardened stainless steel.
Please give your special attention to the cleaning of instruments having inner boreholes and cavities!

Important Notice:

Instruments are non sterile when delivered and sterilisation before use is mandatorily required.

Limitations with reprocessing:

The end of the product's life cycle is determined by the wear and damage from use.

Frequent reprocessing does not affect the performance of these instruments.

Workplace:

Effective hygiene measures according to country-specific guidelines.

Storage and transport:

Immediately after use on patients, place instruments in an instrument tray filled with a suitable cleaner/disinfectant (e.g. KOMET DC1/ alkaline, aldehyde-free). Laying instruments in the media prevents the drying of residues (protein fixation). It is recommended to reprocess the instruments within one hour after use. The transport of the instruments to the reprocessing site should be done using an instrument tray.

Cleaning and disinfection:

As recommended by the Robert Koch Institute (RKI), further processing is, preferably, to be done mechanically.

Validated mechanical processing

Equipment used:

- Cleaning/disinfection device (RDG) (Miele Company with Vario TD Programme)
- 1.5 g/l KOMET DCTherm (DCTherm is only available in Germany!), REF 9872/ mildly alkaline
- Instrument racks for rotary instruments: Nichrominox Company, REF 206002 (h: 4 cm), REF 20600 (h: 5 cm), REF 206004 (h: 7 cm)
- Instrument racks for root canal instruments: Miele Company, REF E 520
- Nylon brushes (e.g. KOMET REF 9873)

Manual pre-cleaning:

1. Take instrument out of the instrument tray immediately before mechanical reprocessing and hold under running water, rotating constantly with the nylon brushes, in order to remove any adhering contamination. Pay close attention to the cleaning of the holes and spaces.
2. Rinse instrument thoroughly with running water so that no cleaner/disinfectant residue gets into the machine.
3. Visually inspect for cleanliness with a suitable magnifying device (experience has shown that an 8 X magnification allows for an optical inspection). If there is residue detected, the cleaning must be repeated until no contamination is visible.

Mechanical processing:

4. Place the instruments in suitable instrument racks.
5. Insert the instrument racks in the RDG in such a manner that the spray directly hits the instruments.
6. Add cleaning powder to the device according to the instructions on the product label and the RDG manufacturer's instructions.
7. Start the Vario TD programme (schematic programme sequence) incl. thermal disinfection. The thermal disinfection is done taking the AO value and the national regulations (DIN EN ISO 15883) into account.
8. After the end of the programme, remove instruments from the RDG and dry (according to RKI recommendation preferably with compressed air). When using instrument racks, pay special attention to the drying of difficult-to-reach areas.
9. Visually check for instrument integrity and cleanliness. If any contamination can still be seen on instrument after mechanical processing, repeat cleaning and disinfecting process until no further contaminants are visible.

Standardized manual processing (alternative)

Equipment Used:

- Nylon brushes (e.g. KOMET REF 9873)
- Suitable cleaner and disinfectant for rotary instruments with confirmed disinfection efficiency (e.g. KOMET DC1, REF 9826 / alkaline, aldehyde-free, alcohol-free, DGHM/VAH-listed)
- Ultrasound device (alternatively: instrument bath)

Processing:

1. Take instrument out of the instrument tray immediately before mechanical reprocessing and hold under running water, rotating constantly with the nylon brushes, in order to remove any adhering contamination. Pay close attention to the cleaning of the holes and spaces.
2. Rinse instrument thoroughly with running water.
3. Visually inspect for cleanliness with a suitable magnifying device (experience has shown that an 8 X magnification allows for an optical inspection). If there is residue detected, the cleaning must be repeated until no contamination is visible.
4. Place instrument in a suitable sieve container which is filled with cleaner and disinfectant into the ultrasound device.
5. For chemical disinfection in the ultrasound device, follow manufacturer's instructions regarding the concentration and residence time. The residence time first begins when the last instrument has been placed in the ultrasound device and may not be shortened under any circumstances. Caution: Do not exceed 45°C (danger of protein coagulation)!
6. Rinse instrument thoroughly after the end of the residence time with suitable water (to prevent residues, if possible rinse with deionised water).
7. Dry instruments (according to RKI recommendation, preferably with compressed air)
8. Visually check instrument for any damage and cleanliness. If residual contaminations are seen on the instrument, repeat cleaning and chemical disinfection until no contamination is visible.

Controls and function inspection:

Instruments which demonstrate the following defects are to be immediately sorted out:

- Dull and chipped or broken edges
- Shape damage (e.g. warped or bent instruments)
- Corroded surfaces

Packaging:

Suitable packaging is to be chosen for the instrument and sterilisation process.
Unit packaging: The packaging must be big enough that the sealing is not stretched.

In a set: Sort instruments into the tray provided or place on an all-propose sterilisation tray. The instruments must be protected. A suitable process is to be used for packing of the trays.

Sterilisation:

Steam sterilisation in a vacuum process at 134°C in a device according to DIN EN 13060; 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

To prevent spot formation and corrosion, the steam must be free of ingredients. The recommended threshold values of the ingredients for feed water and steam condensate are established in DIN EN 13060. When sterilising several instruments, the maximum capacity of the sterilisator must not be exceeded. The instructions of the device manufacturer are to be observed.

Transport and storage:

The transport and storage of the packaged sterilised materials is to be done in a manner which is free of dust, humidity and recontamination.

General remarks:

Comply with the valid, statutory regulations in your country for the reprocessing of medicinal products (e.g. www.rki.de).

On the part of the manufacturer, it is guaranteed that the above-mentioned processing methods are suitable for the processing of the instrument groups named for their reuse. The processor is responsible for the actual reprocessing carried out using equipment, materials and personnel to obtain the desired results in the reprocessing facility. Normally, routine inspections of the validated mechanical or standardised manual reprocessing procedures are necessary. Any deviation of the procedures described (e.g. use of other process chemicals) here are to be carefully evaluated by the processor for their effectiveness and possible negative consequences.

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