EN ISO 17664-1 Manufacturer's instructions for preparing medical devices

Classification under Robert Koch Institut (RKI) guidelines:	HAHNENKRATT Products:
Semi-critical B	Matrix retainer

CE

⚠ Warning

Observe standard accident prevention regulations
We are not aware of any warnings if the devices in question are used in compliance with the instructions for use, and the proper disinfection and cleaning solutions are used.

Before using it for the first time, please pay attention to point "Inspection and functional checks".

Limitation of processing

Reprocessing has little impact. The end of life of the product is determined by wear and tear caused by use.

The end of the product's service life varies from person to person and must therefore be determined by the user. Please see point "Inspection and functional checks".

Instructions

The entire process must also be carried out before first use.

The procedures described here are well known and are based on standard equipment and consumables.

Place of use

The product may only be re-processed in designated rooms/areas. Observe hygiene measures, in accordance with country-specific guidelines.

Storage and transport

The product must be stored in the rooms and transported in the containers provided for this purpose.

Immediately after use on the patient, place the instruments in the instrument tray filled with a suitable cleaning/disinfectant product (e.g. ID 212 from DÜRR, aldehyde-free, alkaline cleaner with a pH value of 10). This prevents residues from drying on the instrument (protein fixation). Please follow the instructions for use of ID 212 regarding dosage and exposure time.

Preparing for decontamination

Follow the standard instructions for instruments in your practice. There are no specific requirements to follow for our HAHNENKRATT instruments.

The Robert Koch Institute (RKI) recommends: Disassembling instruments that can be disassembled while observing personal safety measures.

Cleaning and disinfection

Processing should preferably be carried out by machine as per the recommendation of the Robert Koch Institut (RKI).

A) Validated machine cleaning + disinfection

Processing in the cleaning/disinfecting device (thermodisinfector)

Equipment

1. Cleaning/disinfecting device, e.g. by the company Miele with Vario software. An A_0 value of at least 3000 must be reached.
2. Neodisher® Mediclean Dental by the company Dr. Weigert
3. Neodisher® Z by the company Dr. Weigert
4. Suitable instrument stand or sieve tray

Always follow the instructions for use of the products and devices. Please note DIN EN ISO 15883-1 and DIN EN ISO 15883-2

Information from EN ISO 17664-1:2021, 6.6.2.1: As long as your cleaning/disinfecting device complies with the ISO 15883 series of standards, you can use the programs recommended by the manufacturer and do **not** have to follow our validated reprocessing process. If necessary, please ask us.

Check for integrity and cleanliness using a suitable magnifying glass. 8x magnification should allow visual inspection. If residual contamination can still be seen on the instrument after machine processing, repeat cleaning and disinfection until no contamination is visible anymore.

B) Validated manual cleaning + disinfection

Disinfect and disassemble the instrument prior to manual cleaning.

Cleaning:

Cleaning supply: for example, a nylon brush

Treatment chemicals: ID 212 Forte from DÜRR, alkaline cleaning and disinfecting concentrate with a pH value of 10

It must be ensured that all areas of the instrument can be reached. Clean all joints and joint patches, transitions, hard-to-reach areas as well as the cavities and thread areas particularly carefully.

1. Pre-clean for 1 minute under running drinking water; remove any coarse dirt with a soft brush.
2. Soak in cleaning bath with 2% ID212 Forte for 5 minutes.
3. Clean transitions and thread areas for 15 seconds with a soft brush.
4. Rinse cavities with a syringe.
5. Rinse with drinking water at < 40°C.

After treatment with cleaning and disinfectant solutions, rinse the instruments with tap water.

Check for integrity and cleanliness using a suitable magnifying glass. 8x magnification should allow visual inspection. If residual contamination can still be seen on the instrument after processing, repeat cleaning and disinfection until no contamination is visible anymore.

Disinfection:

Treatment chemicals: ID 212 Forte from DÜRR, alkaline cleaning and disinfecting concentrate with a pH value of 10

Disinfect the instruments as per the instructions for use of the disinfectant and/or cleaning agent. Please refer to the manufacturer's instructions for information on concentration, temperature and contact time.

For disinfection, place cleaned instruments in an ultrasonic bath at room temperature with 2% ID 212 Forte and start the ultrasound.

Application concentration:	2%
Exposure time:	At least 1 minute

It must be ensured that all areas of the instrument can be reached. In particular all joints and joint patches, transitions, hard-to-reach areas as well as the cavities and thread areas.

Rinsing after disinfection should be done for at least 15 seconds with fully desalinated, deionised water in order to avoid lime scale residue on the instrument that leaves white deposits or water spots, for example.

Drying

According to RKI recommendations, dry preferably with medical compressed air. Pay particular attention to drying hard-to-reach areas.

Only put completely dry instruments in the steriliser to avoid, for example, chalky deposits and/or water stains.

Maintenance

The medical device does not require maintenance.

For matrix retainers with screws:
To ensure that the thread runs smoothly, the screws should be sprayed with a turbine oil (including KAVO Universal Spray, Alpro WL-dry). Follow the instructions for use of the products.

Inspection and functional checks

Carry out a visual inspection for defects, damage and wear. For a better visual inspection, a device with optical magnification is recommended. Dispose of faulty and/or defective instruments. For example, instruments with rough and/or protruding corners, edges and screws that are no longer standard.

Packaging

Suitable individual packaging in a sterile film, pursuant to standard EN ISO 11607-1. The packaging must be large enough to prevent the seal from being under any tension. Sterile barrier systems must be checked for integrity before use. If the sterile barrier system is damaged, the packaged goods must be reprocessed.

Validated sterilisation in the autoclave (moist heat)

Pursuant to the RKI, published in Federal Health Bulletin (Bundesgesundheitsblatt) 2012-55:1244-1310 "Hygiene requirements for the preparation of medical devices" page 1248, Table 1 "Risk assessment and classification of medical devices":

Semi-critical B: Sterilisation (X)= optional procedure

Equipment: Steam sterilizer, pursuant to DIN EN ISO 17665 moist heat

Only put completely dry instruments in the steriliser to avoid, for example, chalky deposits and/or water stains.

Procedure:

Steam sterilization using a fractional vacuum process at 134°C in a device pursuant to DIN EN 13060:

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

Observe standard DIN EN ISO 17665 on sterilisation with moist heat.

To avoid staining and corrosion, the steam must not contain any substances. When sterilizing several instruments, the maximum load of the sterilizer must not be exceeded.

Storage

Packaged sterile materials must be transported and stored so that they are protected from dust, moisture and (re)contamination.

It is the responsibility of the body that carried out the final packaging (sterile barrier system or packaging system) in the dental practice to determine how long the sterility of the end product is maintained. (See also "Packaging")

Additional information

All serious events that occur in connection to the product must be reported to the manufacturer and to the competent authority of the Member State where the user and/or patient are based.

Please note the instructions for use of the equipment from the device manufacturer, and do not exceed the maximum load for the device.

Information from EN ISO 17664-1: Biocompatibility can be impaired when rinse aids are used.

Observe national regulations concerning disposal.

These manufacturer's instructions are based on validations carried out by the accredited laboratory Zwisler.

Validation reports:

1910.2975-hahn_auto reprocess.pdf in 2019
1912.0955-hahn_manual reprocess.pdf in 2019
1912.1919-hahn_sterilisation.pdf in 2019

Observe the statutory requirements concerning the reprocessing of medical devices in your country. For more information, visit www.rki.de

The above instructions have been validated by the medical device manufacturer as SUITABLE for preparing a medical device for reuse. It is the responsibility of the processor to ensure that the actual treatment carried out in the preparation area – including the equipment, materials used and personnel – achieves the desired results. This usually requires validation and routine monitoring of the process in the preparation area.

Any deviation from the instructions provided should be assessed with care by the practice Safety Officer for its effectiveness and any potential adverse effects.

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