EN ISO 17664-1 Manufacturer's information
for the processing of resterilizable medical devices

Classification according to RKI-guidelines:	HAHNENKRATT Products:
Semi-critical B	Exatec-S Insertion Tool

CE **Stand 2021-11**

⚠ Warnings

Observe the German standard accident prevention regulations (UVV)
We are not aware of any warnings if the instructions for the devices and disinfection and cleaning agents to be used are followed.

Also observe the point "Inspection and Functional Check" before initial use.

Limitation on reprocessing

Repeated processing has minimal effect. The end of a product's service life is determined by wear and tear and damage due to use.

The end of a product's service life varies and is therefore to be determined by the user.

Instructions

The procedures described are well known and based on standard equipment and consumable materials.

Point of use

Carry out reprocessing only in the rooms/areas designated for this. Observe the effective hygiene measures in accordance with the country-specific guidelines.

Storage and Transport

Storage and transport must carried out in the rooms and containers designated by the practice.

Wet waste disposal
Immediately after the instruments have been used on a patient, place them in a disinfection bath filled with a suitable cleaning/disinfection agent (e.g., ID 212 without aldehyde from DÜRR, alkaline cleaning agent with a pH of 10). This prevents the surface drying of residues (protein fixing). Follow the ID 212 directions for use regarding dosage and application time.

Alternatively:

Dry disposal
Collection of medical devices (dry disposal) after appropriate pretreatment or after patient treatment

Procedure steps from LZK BW AA02-1, 06/2018:

1. Placing the instruments
   in suitable collection containers, e.g. plastic boxes to be sealed

   Careful placing (no throwing in) of the instruments, if necessary with the help of instrument pliers.

   Make sure to use the appropriate personal protective equipment (e.g. hand, eye and mouth/nose protection).

   Long reprocessing should be avoided (recommendation: the 6-hour rule for the waiting time should not be exceeded; manufacturer's instructions should be observed).

2. Sorting out of waste
   in refuse sacks of sufficient strength, leakproof and, if necessary, moisture-resistant.

Preparation for decontamination

Observe the standard instructions for instruments in your practice. For our HAHNENKRATT instruments no other special requirements need to be followed.

The Robert-Koch-Institut (RKI) recommends: Disassembling in accordance with personal protection measures

Automatic processing – cleaning, disinfection, drying

Processing should preferably be done by machine in accordance with the recommendation of the Robert Koch Institute (RKI).

Equipment:

1. Washer/disinfector (W/D) e. g. from the Miele company with a Vario TD program. It must reach an A_0 value of at least 3000.
2. Neodisher® Mediclean Dental from Dr. Weigert company
3. Neodisher® Z from Dr. Weigert company
4. suitable instrument rack or sieve tray

Also follow the instructions for use at all times for the products and devices to be used. Please observe DIN EN ISO 15883-1 and DIN EN ISO 15883-2

Procedure, validated:

1. Take the instruments out of the disinfection bath and rinse thoroughly under running tap water immediately before the automated processing (at least 10 seconds). No residue of the cleaning/disinfection agent should be transferred to the W/D.
2. Place the instruments in a suitable instrument rack of a sieve tray.
3. Place the instrument rack/sieve tray in the W/D so that the spray jet comes into direct contact with the instruments.
4. Start the Vario TD program including thermal disinfection. Thermal disinfection is carried out with an A_0 value of at least 3000.
5. Program:
   - 1 min. pre-washing with cold water
   - Emptying
   - 3 min. pre-washing with cold water
   - Emptying
   - 10 min. washing at 55°C with 0,5% Neodisher® Mediclean Dental alkaline cleaning agent
   - Emptying
   - 3 min. neutralization with warm tap water (>40°C) and 0,1% Neodisher® Z neutralizer; Dr. Weigert, Hamburg
   - Emptying
   - 2 min. intermediate flushing with warm tap water (>40°C)
   - Emptying
   - Thermal disinfection with demineralized water, at 92°C for at least 5 min.
   - Automatic drying, around 60°C for 30 min.
6. Remove the instruments at the end of the program cycle and dry them with compressed air according to the RKI recommendation. With instrument racks/sieve trays pay special attention to the drying of hard-to-reach areas.
7. Check for intactness and cleanliness with a suitable magnifying glass. An 8x magnification is usually sufficient for a visual check. If there is still residual contamination after the automatic processing, cleaning and disinfection should be repeated until all visible traces of contamination have been eliminated.

Information from DIN EN ISO 17664-1: Biocompatibility may be affected by the use of rinse aids.

Manual processing – cleaning

Disinfect instrument prior to manual cleaning.

Cleaning materials: e.g., a soft brush

Treatment chemicals: ID 212 from DÜRR, alkaline cleaning/disinfection agent with a pH of 10

Clean the instruments according to the usage directions for the treatment chemicals and cleaning agents. Please refer to the concentration, temperature and contact time specified by the manufacturer of the cleaning agent.

It is necessary to ensure that all areas of the instrument are reached. Clean particularly carefully all joints, transitions, areas difficult to access as well as the cavities and thread areas.

1. Pre-wash for 1 minute under running potable water with a soft brush to remove coarse impurities.
2. Place in ID 212 cleaning solution at 2% concentration for 5 minutes.
3. Clean transitions and threaded areas with a soft brush.
4. Rinse hollow openings with syringe.
5. Rinse with tap water < 40°C

Check for intactness and cleanliness with a suitable magnifying glass. An 8X magnification is usually enough for a visual check. If there is still residual contamination after the processing, cleaning and disinfection should be repeated until all visible traces of contamination have been eliminated.

Information from DIN EN ISO 17664-1: Biocompatibility may be affected by the use of rinse aids.

Manual processing – disinfection

Treatment chemicals: ID 212 from DÜRR, alkaline cleaning/disinfection agent with a pH of 10

Disinfect the instruments according to the usage directions for the disinfection and/or cleaning agents. Please refer to the concentration, temperature and contact time specified by the manufacturer of the cleaning agent.

Place cleaned instruments for disinfection in an ultrasonic bath at room temperature with 2% ID 212 Forte and start ultrasonics.

Application concentration:	2%
Exposure time:	Minimum 1 minute

It is necessary to ensure that all areas of the instrument are reached. Especially all joints, transitions, areas difficult to access as well as the cavities and threaded areas.

After disinfecting, rinsing should be done with fully desalinated, deionized water for at least 15 seconds in order to prevent lime scale residues on the instrument, which leave behind white deposits or water spots.

Information from DIN EN ISO 17664-1: Biocompatibility may be affected by the use of rinse aids.

Manual processing – drying

Preferably with compressed air according to RKI recommendation. With instrument racks, pay special attention to the drying of hard-to-reach areas.

Only put completely dry instruments in the sterilizer in order to prevent lime scale deposits and/or water spots.

Maintenance

The medical device does not require maintenance.

Inspection and functional check

Carry out a visual inspection for non-conformances, damages and wear and tear. It is recommended to use a device with optical magnification for better visual inspection. Faulty and/or defective instruments should be discarded. This includes instruments with rough and/or protruding corners, edges, etc.

Packaging

Use standardized packaging material (DIN EN ISO 11607-1) designed for this purpose. The packaging must be large enough so that no stress is placed on the seal.

Sterilization

According to RKI published in German Federal Health Gazette 2012-55:1244-1310 "Hygiene requirements for the reprocessing of medical devices," page 1248, Table 1. Risk assessment and classification of medical devices:

Semi-critical A: Sterilization (X) = optional step
Critical A: Sterilization X = Generally sterilization with moist heat

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

Only put completely dry instruments in the sterilizer in order to prevent lime scale deposits and/or water spots.

Procedure:

Steam sterilization using a fractionated vacuum method at 134°C in a device in accordance with EN 13060:

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

Observe standard DIN EN EN 17655 for sterilization with moist heat.

In order to prevent spot formation and corrosion, the steam have to be free of any other substances. The maximum load for the sterilizer must not be exceeded when sterilizing several instruments.

Follow the instructions for use of the device manufacturer as well as the manufacturer of the sterile packaging.

Storage

The packaged sterile goods must be protected from dust, humidity and (re)contamination during transport and storage.

Additional information

Any serious incidents that occur in connection with the product must be reported to the manufacturer and to the competent authority of the member state in which the user and/or patient is located.

Ensure that the maximum load of the devices is not exceeded.

The entire procedure must also be carried out before initial use.

Observe the national regulations for disposal.

The basis for this manufacturer information are validations carried out by the accredited Zwisler laboratory.

Validation report:

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

Manufacturer contact

E. HAHNENKRATT GmbH
Dentale Medizintechnik
Benzstraße 19
DE-75203 Königsbach-Stein
GERMANY
Tel +49 7232 3029-0
info@hahnenkratt.com
www.hahnenkratt.com

Observe your country's applicable legal requirements for the reprocessing of medical devices. You can find information about this at www.rki.de.

The instructions provided above have been validated by the medical device manufacturer as being SUITABLE for the preparation of a medical device for reuse. It is the responsibility of the user to ensure that the carried out processing performed in the processing area in the practice – including the professional equipment, materials and personal used – achieves the desired result. This usually requires validation and routine monitoring of the procedure in the processing area in the practice.

Any deviation from this provided instructions should be carefully evaluated for effectiveness and any possible negative consequences by the practice's safety officer.