EN ISO 17664-1 Manufacturer's information on the processing of medicinal products

Classification in accordance with RKI Guideline:	HAHNENKRATT Products:
Critical A	Rotating stainless steel instruments for Exatec, Cytec, Contec Root post systems ExaPin + SHARPcut

CE 0197 **Status 2021-11**

⚠ Warning

Please observe the standard accident prevention regulations (UVV).
Warnings are not known to us if the user manuals of the devices to be used are observed and the treatment chemicals to be used are applied.

Before first use, please observe the item "Inspection and function test".

Limitations during processing

The end of the service life of the product is determined by wear and damage as a result of use.

The end of the service life of the product differs individually and must therefore be determined by the user. Please observe the item "Inspection and function test".

Instructions

The entire process must also be performed prior to first use.

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

Place of use

Re-processing may only be carried out in the rooms/areas designated for the purpose. Observe the hygiene-related measures in accordance with the country-specific regulations.

Storage and transport

Immediately after use on the patient, place the instruments into the 'Fräsator' (bur disinfector) filled with a suitable cleaning agent/disinfectant (alkaline, aldehyde-free) to prevent residues from drying on (protein fixation). It is recommended to process the instruments at the latest one hour after use. Transport to the reprocessing site should take place in the Fräsator.

Preparation for decontamination

Please also observe the instructions for rotating instruments commonly applied in your practice. HAHNENKRATT rotating instruments are not subject to any particular requirements.

Cleaning and disinfection

In accordance with the recommendation of the Robert-Koch-Institute (RKI), mechanical processing is preferable.

A) Validated mechanical cleaning + disinfection

Processing in the WDD (thermal disinfector)

Equipment

1. Washing/disinfecting device (WDD) as per EN ISO 15883, e.g. Miele brand with Vario TD programme. A minimum A_0 value of 3000 must be achieved.
2. Neodisher® Mediclean Dental from the Dr. Weigert Company
3. Neodisher® Z Dental from the Dr. Weigert Company
4. WDD basket insert suitable for drills

Please also always observe the user manuals for the products and devices to be used. Please observe DIN EN ISO 15883-1 and DIN EN ISO 15883-2.

WDD procedure, validated:

1. Place the instruments in a suitable basket insert.
2. Fill the basket insert and place it in the WDD as recommended by the manufacturer of the WDD. The spray jet must be able to come into direct contact with the instruments.
3. Fill the WDD with cleaning agent/disinfectant as specified in the manufacturer's instructions and as specified by the WDD manufacturer.
4. Start the Vario TD programme including thermal disinfection. Thermal disinfection takes place taking the A_0 value of at least 3000 into consideration.
5. Programme:
   - Pre-rinse for 1 min. with cold water (<40°C drinking water quality)
   - Emptying
   - Pre-rinse for 3 min. with cold water (<40°C drinking water quality)
   - Emptying
   - Wash for 10 min. at 55°C with 0.5% alkaline cleaner Neodisher® Mediclean Dental
   - Emptying
   - Neutralisation for 3 min. with warm tap water (>40°C) and 0.1% neutraliser Neodisher® Z Dental, Dr. Weigert, Hamburg
   - Emptying
   - Intermediate rinsing for 2 min. with warm tap water (>40°C)
   - Emptying
   - Thermal disinfection with demineralised water, temperature 92°C for at least 5 min.
   - Automatic drying, 30 min. at 90°C

After the programme has finished running, remove the instruments from the WDD and dry them as per KRINKO recommendations, preferably with medical compressed air. Ensure that areas are also dry that are difficult to reach.

B) Validated manual cleaning + disinfection

Processing respectively in an ultrasonic bath

Equipment

1.	Cleaning agent:	1) Ultrasonic bath 2) Nylon brush
2.	Cleaning agent:	ID 220 by DÜRR (aldehyde-free ready-to-use solution/drill bath) Ultrasound-suitable disinfectant for rotating instruments

Procedure, validated:

Manual cleaning with ultrasound and brush

Take the instrument out of the 'Fräsator' and clean it in a suitable sieve container for 15 min in an ultrasonic cleaning bath at room temperature. Make sure that all accessible surfaces are moistened and that acoustic shadowing is avoided.

Then clean the instrument with a nylon brush in the solution (without ultrasound) until there are no more residues visible on the surface.

It must be ensured that <u>all</u> areas of the instrument are reached and cleaned.

Manual disinfection with ultrasound

Place the instrument in a suitable sieve container for 1 minute in a freshly prepared ultrasonic bath with 100% ID 220 for disinfection (<45°C).

Rinse the instrument thoroughly for 1 minute with fully demineralised deionised water.

If applicable, completely remove any remaining contamination with the nylon brush while continuously rotating the instrument. Then rinse under running water and repeat ultrasonic cleaning and disinfection.

Dry the instrument as per KRINKO recommendations, preferably with medical compressed air. Ensure that areas are also dry that are difficult to reach.

Maintenance

The medicinal product does not require maintenance.

Inspection and function test

Visual inspection for intactness and cleanliness. An 8-fold magnifying effect generally enables visual inspection. If visible contamination residues are still visible on the instrument after processing, repeat the cleaning and disinfection procedure until signs of contamination are no longer visible.

Immediately sort out and dispose of instruments with the following defects:

- Blunt and broken blades
  The blades unavoidably become increasingly blunter as a result of use. The instruments must always be disposed of when use is restricted by blunt or broken blades.
- Damage to the shape (e.g. bent instruments)
- Corroded surfaces

Packaging

Suitable individual packaging in a sterilisation wrap as per DIN EN ISO 11607-1. The packaging must be adequately sized, so that the sealing is not under tension.

Validated sterilisation in the autoclave (moist heat)

Equipment: Steam steriliser, as per DIN EN ISO 17665 moist heat

Procedure, validated:

Steam sterilisation in a fractionated vacuum procedure at 134°C in a device as defined by DIN EN 13060:

1. Fractionated prevacuum (at least 3-fold)
2. Sterilisation temperature 134°C
3. Hold time: 5 minutes (full cycle)
4. Drying time: 10 minutes

Please observe the standard DIN EN ISO 17665 for sterilisation with moist heat.

To avoid stain formation and corrosion, the steam must be free of constituents. When several instruments are sterilised, the maximum load of the steriliser must not be exceeded.

Storage

The packaged sterile product must be protected against dust, moisture and (re)contamination for transport and storage.

Additional information

All serious incidents that occur in connection with the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is registered.

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Please observe the instructions for use issued by the manufacturer(s) of the products and ensure that the maximum load of the devices is adhered to.

Information from DIN EN ISO 17664-1:Biocompatibility may be impaired if rinsing agents are used.

Please observe the national regulations for disposal.

Please observe the legal provisions for the reprocessing of medicinal products applicable in your country. Information is available at www.rki.de, for example.

The instructions listed above have been validated as SUITABLE for preparing a medicinal product for reuse by the manufacturer of the medicinal product. The processor is responsible for ensuring that the actual processing carried out - with the equipment, materials and personnel deployed - obtains the desired results in the processing facility. This usually requires validation and routine monitoring of the procedure in the processing facility.

Any deviation from these instructions should be carefully evaluated by the safety officer of the practice in terms of efficacy and potential negative consequences.

This manufacturer's information is based on validations performed at the Zwisler accredited laboratory.

Validation reports 2021:
2106.1499-hahnenkratt_manuell
2106.1495-hahnenkratt_automatisch
2106.0929-hahnenkratt_Sterilisation

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