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

Classification in accordance with RKI Guideline:	HAHNENKRATT Products:
Critical A	Exatec, Cytec, Contec Root posts made of titanium and HT-glass fibre ExaPin

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CE 0197

⚠ 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 disinfection and cleaning solutions to be used are applied.

Root posts must be disinfected and sterilised prior to single use.

Root posts are not reusable. Unauthorised reuse would pose a risk of cross-contamination. Multiple processing poses a risk of deterioration of the materials.

Check that the product is intact before use.

Limitation during processing

Root posts are designed for single use only, not for reuse.

Instructions

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

Place of use

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

Storage and transport must take place in the rooms and containers provided by the practice.

Preparation for decontamination

Please also observe the instructions for root posts commonly applied in your practice. These are standard root posts for which no particular preparation is required.

Cleaning, disinfection and drying

Mechanical processing

N/A

Cleaning, disinfection and drying

Validated manual processing

Treatment agent: 70% ethanol/water mixture as per DAB (German Pharmacopoeia)

Procedure, validated:

1. Take the root post out of the packaging.
2. Place the root posts in 70% ethanol/water mixture as per DAB for
3. 10 minutes for cleaning and disinfection - ensure that all areas are covered.
4. If applicable, allow any excess ethanol to evaporate until no residual moisture remains.

Maintenance

The medicinal product does not require maintenance.

Inspection and function test

Visual inspection for intactness and cleanliness prior to use. An 8-fold magnifying effect generally enables visual inspection. If applicable, dispose of damaged root posts.

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.

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.

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.

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 processing 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:

HT Glasfiber 2201.1085-hahnenkratt_manuell
2112.2139-hahnenkratt_steri

Titan	2111.2265-hahnenkratt_manuell
	2111.1109-hahnenkratt_steri

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