INSTRUCTIONS FOR USE
EXATEC, CYTEC and CONTEC TITANIUM+ HT GLASS FIBRE

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The instructions for use and all EN ISO 17664-1 can also be downloaded at www.hahnenkratt.com/service.

According to the MDR (EU) 2017/745, we are required to inform you about the revised eIFU. To do this, please register at www.hahnenkratt.com/service.

Intended users
These products are intended for dental use only. They are used exclusively by the dentist.

Target group of patients
Patients with teeth showing signs of severe coronal damage as well as patients with root-treated teeth. In the case of children or adolescents, the user must take care to treat only permanent teeth, as a root post in a milk tooth would interfere with the tooth change, since the root of the milks tooth is absorbed by the permanent tooth during dentition.

Clinical benefit
Restoration with root posts avoids extraction of the tooth. By using canal enlargers and calibration drills coordinated to the root posts, as much of the healthy tooth substance as possible can be preserved and the root canal is prepared in a shape congruent to the root post. By means of the congruent shape, the root post or the restoration is therefore given the best possible fit, thus optimising the fracture resistance and service life.

Purpose
Root posts are indicated for anchoring restoration structures in devitalised permanent teeth that have suffered severe coronal damage. Root posts are intended for single use only. The canal enlargers and calibration drills are intended to prepare the root canal for the subsequent restorative measures. The field of application of the drills is the preparation of the root canal for the accommodation of a root post.

Contraindication
We have no knowledge of any contraindications for our drills and root posts, provided that the treatment is carried out professionally after undergoing preparation in accordance with our Manufacturer's information EN ISO 17664-1.

Please also observe the item "Precautions and Sources of Error".

Undesirable side effects
Are not known, provided that the treatment is carried out professionally and in accordance with our instructions for use.

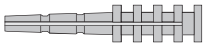
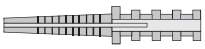
Disposal
Please observe the national and regional regulations for disposal.

The shanks
The drill shanks are designed in accordance with EN ISO 1797 type 1 and only fit into the contra-angle handpiece provided.

Our HAHNENKRATT calibration drills are shape congruent to the size of the respective HAHNENKRATT root post. Please refer to the following tables for each root post system

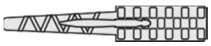
The final recipient site of the post can only be calibrated with the appropriate size of the calibration drill.

EXATEC, EXATEC-S TITANIUM

Exatec Titanium Modular root post system		Post head Ø apic. Post length apic. Post Ø ▲ apic. Post Ø ▼ mm	universal	2.6 6.6 1.461 0.98 mm	2.7 8.0 1.559 0.98 mm	2.8 9.7 1.681 0.98 mm	3.0 11.4 1.803 0.98 mm
		Coding	none	white	yellow	blue	black
Instruments, universal for all modules		**Content**	**REF**				
	Canal enlarger with centring tip	1	42010				
	Canal enlarger with cutting tip	1	43000				
	Pilot drill	1	42100				
	Calibration drill	1		42001	42002	42003	42004
	Measuring template	1	42050				
Exatec							
	Root post	10		42311	42312	42313	42314
System Box + Organizer, empty		1	10004 + 10000				
Exatec-S							
	Root post	10		45511	45512	45513	45514
	Insertion tool	1	45522				
System Box + Organizer, empty		1	10005 + 10000				

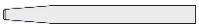
EXATEC BLANCO, HT GLASS FIBRE

Exatec Root post system		Post head Ø apic. Post length apic. Post Ø ▲ apic. Post Ø ▼ mm	universal	2.6 6.6 1.461 0.98 mm	2.7 8.0 1.559 0.98 mm	2.8 9.7 1.681 0.98 mm	2.2 – – 0.98 mm
		Coding	none	white	yellow	blue	green
		Content	**REF**				
	Canal enlarger with centring tip	1	42010				
	Canal enlarger with cutting tip	1	43000				
	Pilot drill	1	42100				
	Calibration drill	1		42001	42002	42003	
	Calibration drill	1					42005
	Measuring template	1	42050				

Exatec blanco							
	Root post	10		42611	42612	42613	
	Root post	10					42615
System Box		1	10003				

CYTEC, HT GLASS FIBRE

Cytec root post system			universal	1.0 mm	1.2 mm	1.4 mm	1.6 mm	1.8 mm	2.1 mm
		Coding	none	red	white	yellow	green	blue	black
		Content	**REF**						
	Canal enlarger with centring tip	1	42010						
	Canal enlarger with cutting tip	1	43000						
	Calibration drill	1		4300D10	43001	43002	4300D16	43003	43004
	Measuring template	1	43050						

Cytec root post system			universal	1.0 mm	1.2 mm	1.4 mm	1.6 mm	1.8 mm	2.1 mm
		Coding	none	red	white	yellow	green	blue	black
		Content	**REF**						
Cytec									
	Root post	10		4360D10	43601	43602	4360D16	43603	43604
	Root post eco	5		4370D10	43701	43702	4370D16	43703	43704
System Box		1	10001						

CONTEC, HT GLASS FIBRE

Contec root post system			universal	1.1 mm	1.3 mm	1.5 mm	1.75 mm	2.0 mm
		Coding	none	red	white	yellow	blue	black
		Content	**REF**					
	Canal enlarger with centring tip	1	42010					
	Canal enlarger with cutting tip	1	43000					
	Calibration drill	1		4400D11	44001	44002	44003	44004
	Measuring template	1	44050					
Contec								
	Root post	10		4460D11	44601	44602	44603	44604
	Root post eco	5		4470D11	44701	44702	44703	44704
System Box		1	10002					

MATERIALS

Titanium Grade 5: Ti 6-Al 4-V alloy according to DIN EN ISO 5832-3, US standard ASTM F 136

Fibre composite materials: HT glass fibre (FRC, Fibre Reinforced Composite)

PREPARATION

EN ISO 17664-1 Manufacturer's information attached + download at www.hahnenkratt.com/service

The rotating instruments and the root posts are supplied in **non-sterile** condition. The packaging is **not** suitable for sterilisation.

The rotating instruments must be processed prior to each use and also prior to first use, in accordance with our EN ISO 17664-1 Manufacturer's information for the processing of medical devices - rotating instruments.

The end of the service life of the product is determined by wear resulting from use.
In order to achieve optimum drilling performance and to avoid potential hazards caused by blunt or damaged instruments, the instruments must be inspected prior to each use in accordance with EN ISO 17664-1 Manufacturer's information for the processing of medical devices - rotating instruments (see "Inspection and function test").

The root posts must be processed before use in accordance with EN ISO 17664-1 Manufacturer's information for the processing of medical devices - Root posts. The root posts are not designed for reprocessing or reuse. Unauthorised multiple reuse poses a risk of cross-contamination. Multiple processing poses a risk of deterioration of the materials.

Our system boxes offer the dentist clear organisation during treatment and the possibility to easily take out the drills and root posts for treatment:

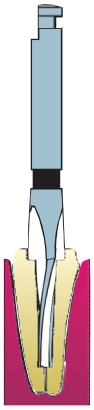
Exatec (REF 10004), Exatec-S (REF 10005),
Exatec Fiber (REF 10003), Cytec (REF 10001), Contec (REF 10002)

The number and size of the root posts are determined based on the X-ray image. At the treatment unit, the required **sterilised** root posts and **sterilised** drills are taken out of the sterile barrier system and placed in the **sterilised** system box.

OVERVIEW: DISINFECTION / CLEANING / STERILISATION

X = applicable	**Root posts Titanium**	**Instruments Drills**	**Root posts HT glass fibre**
Disinfection:			
Disinfection, manual	X	X	X
Thermal disinfection (WDD)	-	X	-
Cleaning, manual:			
70% ethanol water mixture as per DAB (German Pharmacopoeia)	X	-	X
Sterilisation:			
Autoclave	X	X	X

PREPARATION OF THE ROOT CANAL



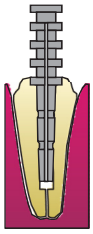
Initial situation:

The tooth must be professionally pretreated and must not show any indications of pathological change. The root canal lumen must have a linear path and must be processed with the calibration drill up to max. 3 mm to the physiological foramen for the accommodation of the root post.

- The post size is determined by the measuring template. For this purpose it is placed on the X-ray image. When performing digital X-rays, a digital measurement must be taken in order to establish the correct post size.
- Apply rubber dam
- Opening and enlargement of the root canal with manual instruments up to around ISO 80.
  The widest possible processing using manual instruments reduces the use of drills, which can generate heat that may damage the dentine.
- Machine enlargement of the root canal lumen with the canal enlarger (REF 43000 or REF 42010) and, when using Exatec, subsequently with the pilot drill (REF 42100). Observe the selected post length and mark it with a rubber ring on the drill, if necessary.
- Calibration drilling of the recipient site of the post with the calibration drill in such a way that, when using Exatec, the support for the post head has a depth of at least 2mm in the dentine.
  - *The integrated end cutter ensures that the support runs centrally and at a right angle to the canal axis.*
  - *In order to avoid damage to the root dentine due to the development of heat, root canal drills should generally only be used*

    - ***while cooling by water or gel***
    - ***at a speed of 500-1000 rpm.***
    - ***in a "dabbing" manner, while applying as little pressure as possible***
  - *Inspect the instruments at intervals.* ***Remove any drilling chips and clean off any abrasion. Rinse the drilled channel.***
- Clean and dry the root canal.

INSERTION: EXATEC, TITANIUM



- Insert the Exatec titanium root post to try out the fit and check the bite.
- If necessary, mark the required post height and shorten the post head extra-orally using a fine-grain silicone carbide grinding instrument, thin carbide cutter or cutting disc in the handpiece.
- Clean the root canal:
    - Rinse with e.g. 37% phosphoric acid, NaOCl, H_2O_2
    - If applicable, remove and condition the smear
    - Dry with paper tips, then finish with warm air

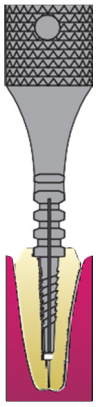
      !! Caution: Avoid temporary cements containing eugenol or remove them **completely**. NaOCl or H_2O_2 are not indicated when composites are used, as the nascent oxygen can trigger oxygen inhibition of the curing of the composite.

- Clean the shortened Exatec root post using 70% ethanol/water mixture as per the DAB (German Pharmacopoeia).
- Fill the root canal with **low-viscosity** cement in portions using a paste carrier, so that no air pockets develop**.** Only low-viscosity cement can flow sufficiently through the drainage grooves of the post.

  Phosphate or glass ionomer cements and composites are suitable as luting agents. Materials with a small filler grain size (0.1-1.2µm) are to be preferably used (Ketac™ Cem radiopaque, 3M™).
- Slowly screw the Exatec root post into the root canal with a smooth turning motion until the post head rests firmly in the post head support.
- Allow the luting agent to harden.
- Remove any excess luting agent
- If necessary, adjust the post head according to the contact situation with cylindrical diamonds applying water cooling.

Structure and final restoration as per the package leaflet of the products and procedures to be used.

INSERTION: EXATEC – S, TITANIUM



- Mount the Exatec-S root post on the insertion tool:
  - Precautionary measure: Secure the insertion tool with a safety chain (pull through the drilled hole)
  - Place the insertion tool onto the post
  - Turn the insertion tool until the grooves engage
  - Insert the post
  - **Check the firm seating of the post in the insertion tool**
- Screw in the Exatec-S root post to try out the fit
  - *The self-cutting "claws" cut their way into the dentine. A engage threads ll minimal comparatively a with possible is insertion and cone the through simultaneously .turns* 3 *of maximum a with* 1.7*Ncm*±7.9 *of torque *) The apical movement of the post is stopped exactly by the accurately fitting support.*
- Clean the root canal:
  - Rinse with e.g. 37% phosphoric acid, NaOCl, H_2O_2
  - If applicable, remove and condition the smear
  - Dry with paper tips, then finish with warm air

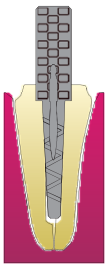
    !! Caution: Avoid temporary cements containing eugenol or remove them **completely**. NaOCl or H_2O_2 are not indicated when composites are used, as the nascent oxygen can trigger oxygen inhibition of the curing of the composite.
- Clean the Exatec-S root post, removing dentine chips while doing so using 70% ethanol/water mixture as per the DAB (German Pharmacopoeia).
- Fill the root canal with **low-viscosity** cement in portions using a paste carrier, so that no air pockets develop**.** Only low-viscosity cement can flow sufficiently through the drainage grooves of the post.
  - *Phosphate or glass ionomer cements and composites are suitable as luting agents.* Materials with a small filler grain size (0.1-1.2µm) are to be used. *(Ketac™ Cem radiopaque, 3M™)*
- Screw in the Exatec-S root post:

  Start with a small counterclockwise turn so that the post engages in the pre-cut threads, then turn clockwise to screw in the root post (max. 3 turns).
- Pull off the insertion tool in axial direction to the post in order to avoid deformation of the "claws".
- Allow the luting agent to harden and remove any excess luting agent.
- Adjust the post head according to the contact situation with cylindrical diamonds applying water cooling.

Structure and final restoration as per the package leaflet of the products and procedures to be used.

*) established in a comparative dissertation in 1994
"Torque measurements on screwable root canal post systems" by Klaus Gabert

INSERTION: EXATEC, CYTEC, CONTEC HT GLASS FIBRE



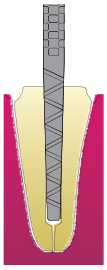
Exatec

- Insert the root post to try out the fit and check the bite.
- Mark the required post height (contact height) and shorten extra-orally using a fine diamond disc. While doing so, avoid dust development (use sharp cutting instructions).

  !! Caution: **Never** use pliers for shortening. This would damage the structure of the material.

- Clean the root post using 70% ethanol/water mixture as per the DAB (German Pharmacopoeia).
- Prepare the root canal: Condition the dentine with the adhesive technique

  !! Caution: Avoid temporary cements containing eugenol or remove them completely. H_2O_2 or NaOCI are not indicated, as the nascent oxygen can trigger oxygen inhibition of the curing of the composite.



Cytec

Adhesive technique, for example:

- Condition the canal and the tooth surface (e.g. 37 % phosphoric acid)
- Remove the acid with water spray
- Flush the canal with alcohol (e.g. 70 %)
- Dry the canal with paper tips
- Apply the primer and take up any excess with paper tips
- Apply the bonder and take up any excess with paper tips
  !! Caution: Do **not** polymerise the bonder using light.

- Optional: Apply a **thin** layer of dual-curing bonder top the post; do **not** polymerise using light.
  Alternative: *Apply a **thin** layer of dual-curing bonder to the post, blow out **very thin** and polymerise using light, e.g. CLEARFILTM Universal Bond Quick, Kuraray.*

Contec

- Fill the root canal with **low-viscosity, dual-polymerising, X-ray visible composite** using a paste carrier. Observe the instructions for use of the composite manufacturer e.g.: PANAVIA™ F 2.0, Kuraray
- Quickly apply composite to the root post and insert it **slowly** into the root canal with a smooth turning movement, then hold it in position until the composite has hardened enough to enable the firm seating of the post.
- Distribute any excess material evenly over the protruding post and cavity and remove any remaining excess composite.
- Harden using a polymerisation lamp for approx. 40 seconds (follow the instructions for use of the composite).
- Then build the stump quickly with viscous composite. If necessary, use a transparent sleeve (frasaco) or matrix tape (HAHNENKRATT) to shape the structure.
  e.g.: CLEARFIL™ DC CORE PLUS, Kuraray
- Make final fine corrections with a turbine and a diamond-coated grinding tool while cooling with water.

Please observe the instructions for use of the products and devices to be used.

PRECAUTIONS AND SOURCES OF ERROR

Taking into account the clinical situation and the indication, it must be kept in mind that there are limits to the break resistance and flexural strength of a fabricated root post due to the material and the selected post diameter.

But regarding the other components: remaining hard tooth substance or structure and crown can also be the cause of the failure of a restoration.

In the information on preparation and insertion, points have already been listed that have a positive impact on the stability of the restoration. The careful grinding of a balanced contact is of great importance for the stability of the restoration and its service life. The dynamic loading by the antagonists must be kept as low as possible. Incorrect or excessive loading can cause restorations to come loose, to shift orthodontically or even to break.

The preparation in the crown margin area should take place in such a way that the stability of the restoration can be supported by the so-called ferrule effect.

SOURCES OF ERROR

The failure of a restoration is shown by:	**Possible causes**:
A) Loosening or detachment of the root post	• Incorrect bonding between luting material + dentine (inadequate preparation of the root canal).
B) Breakage of the root post	• see A) • Too high dynamic load due to the antagonists (see above) • Excessive, sudden load • Selection of an under-dimensioned root post
C) Fissuring or fracturing of the root	• see B) • Sclerotic root dentine

PRECAUTIONS

The root post is not reusable.
Unauthorised reuse would pose a risk of cross-contamination.

Please also observe the information from the two enclosed EN ISO 17664-1 Manufacturer's information sheets for the processing of medical devices.

ADDITIONAL INFORMATION

All serious incidents occurring 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.

The Safety and Clinical Performance Summary Report (SSCP) of the root canal posts is made available via EUDAMED. Until the functional capability of the corresponding EUDAMED module is achieved, the SSCP is available from the manufacturer upon request within 7 calendar days.

www.hahnenkratt.com/service

A free copy of >>IFU + EN ISO 17664-1 Manufacturer's information on processing<< is available within 7 calendar days upon request from:

MANUFACTURER

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SYMBOLS

	Do not reuse		Article number
	Consult instructions for use		Batch codes
	Consult electronic instructions for use Download at: www.hahnenkratt.com/service		Date of manufacture
	Caution		Manufacturer
	Packaging unit		Clockwise rotation
	Medical Device		Keep dry
	Unique identifier of a medical device		Non-sterile
	Do not use if the packaging is damaged and observe the instructions for use		

⚠ 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, e.g. Miele insert, article E491

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

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 at least 15 minutes 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 at least 1 minute in a freshly prepared ultrasonic bath with 100% ID 220 for disinfection (<45°C).

Rinse the instrument thoroughly for at least 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 their use is limited 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 EN ISO 11607-1. The packaging must be adequately sized, so that the sealing is not under tension. Sterile barrier systems must be checked for intactness prior to use. If the sterile barrier system is damaged, the packaged product must be re-processed.

Validated sterilisation in the autoclave (moist heat)

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

Procedure, validated:

Steam sterilisation in a fractionated vacuum procedure at 134°C in a device in accordance with EN 13060:

1. Fractionated prevacuum (at least 3-fold)
2. Sterilisation temperature 134°C (-0/+3°C)
3. Hold time: at least 5 minutes (full cycle)
4. Drying time: at least 10 minutes

Please observe the standard 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.

The determination of the duration of the maintenance of sterility of the end product is the responsibility of the body that performed the final packaging (sterile barrier system or packaging system) in the dental practice. (See also "Packaging")

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 of the operating media used and of the manufacturers of the products and ensure that the maximum load of the products is observed.

Information from 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 processing 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.

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⚠ 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 intended for single processing.

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

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. Insert for at least 10 minutes for disinfection - ensure that all areas are covered.
4. Allow 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 EN ISO 11607-1. The packaging must be adequately sized, so that the sealing is not under tension. Sterile barrier systems must be checked for intactness prior to use. If the sterile barrier system is damaged, the packaged product must be re-processed.

Validated sterilisation in the autoclave (moist heat)

Equipment: Steam steriliser, as per 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 (-0/+3°C)
3. Hold time: at least 5 minutes (full cycle)
4. Drying time: 10 minutes

Please observe the standard 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.

The determination of the duration of the maintenance of sterility of the end product is the responsibility of the body that performed the final packaging (sterile barrier system or packaging system) in the dental practice. (See also "Packaging")

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 of the operating media used and of the manufacturers of the products and ensure that the maximum load of the products is observed.

Please observe the national regulations for disposal.

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

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⚠ Warning

Please observe the standard accident prevention regulations (UVV).
Warnings are not known to us if the user manuals of the products to be used are observed and the disinfection and cleaning solutions to be used are applied.

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

Limitation during processing

Reprocessing has little effect. 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.

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

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

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

Alternative:

Dry disposal
Collect the medicinal products (dry disposal) after appropriate pre-treatment or after patient treatment

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

1. Deposit the instruments
   in suitable collection containers, e.g. lockable plastic boxes.

   Carefully deposit the instruments (do not throw in), if necessary using instrument tongs.

   Attention must be paid to the appropriate personal protective equipment (e.g. protection of the hands, eye and mouth/nose).

   Avoid long processing times (recommendation: the 6-hour waiting time rule should not be exceeded; observe the manufacturer's instructions).

2. Sort out waste
   in sufficiently resistant, leak-tight and, if necessary, moisture-resistant waste bags.

Preparation for decontamination

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

The Robert Koch Institute (RKI) recommends: Disassembly of instruments that can be dismantled, while observing personal protection measures.

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) e.g. Miele with Vario programme. A minimum A_0 value of 3000 must be achieved.
2. Neodisher® Mediclean Dental, Dr. Weigert Company
3. Neodisher® Z, Dr. Weigert Company
4. Suitable instrument stand or sieve tray

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

Procedure, validated:

1. Immediately before machine processing, remove the instruments from the instrument tray and rinse thoroughly under running drinking water (for at least 10 seconds). No residues of the cleaning agent/disinfectant should be transferred to the WDD.
2. Place the instruments in a suitable instrument stand or sieve tray.
3. Place the instrument stand/sieve tray in the WDD in such a way that the spray jet hits the instruments directly.
4. Start the Vario 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
   - Emptying
   - Pre-rinse for 3 min. with cold water
   - 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, 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 approx. 60°C
6. After the programme has finished, remove the instruments from the WDD and dry them as recommended by the RKI, preferably with compressed air. In the case of instrument stands/sieve trays, pay particular attention to the drying of areas that are difficult to reach.
7. Inspection for intactness and cleanliness with a suitable magnifying object. An 8-fold magnifying effect generally enables a visual inspection. If residual contamination is still visible on the

instrument after machine processing, repeat the cleaning and disinfection procedure there are no more signs of visible contamination.

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 + drying

Before manual cleaning, disinfect the instrument.

Processing respectively in an ultrasonic bath

Equipment

1. Cleaning agent:	1) Ultrasonic bath 2) Nylon brush
2. Chemicals for treatment:	ID 212 Forte from DÜRR, alkaline cleaning and disinfection concentrate with a pH value of 10.

Manual cleaning with ultrasound and brush

Clean the instrument in a suitable sieve container for at least 15 minutes in an ultrasonic cleaning bath at room temperature. Make sure that all accessible surfaces are moistened and that acoustic shadowing is avoided. Please observe that the two cavities have an opening on both sides to allow rinsing.

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 all areas are reached and cleaned, in particular areas that are difficult to reach and grooves of the instrument.

Manual disinfection with ultrasound

Place the instrument in a suitable sieve container for at least 1 minute in a freshly prepared ultrasonic bath with 100% ID 212 for disinfection (<45°C).

Rinse the instrument thoroughly for at least 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 a visual inspection. If residual contamination is still visible on the instrument after processing, repeat the cleaning and disinfection procedure there are no more signs of visible contamination.

Instruments with defects, such as bent or broken claws, must be disposed of.

Packaging

Suitable individual packaging in a sterilisation wrap as per EN ISO 11607-1. The packaging must be adequately sized, so that the sealing is not under tension. Sterile barrier systems must be checked for intactness prior to use. If the sterile barrier system is damaged, the packaged product must be re-processed.

Validated sterilisation in the autoclave (moist heat)

According to the RKI published in the Bundesgesundheitsblatt (Federal Health Bulletin) 2012-55:1244-1310 "Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten" (Requirements on hygiene in the processing of medicinal products) page 1248, Table 1 Risk assessment and classification of medicinal products:

Semi-critical B: Sterilisation (X)= Work step is optional

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

Only place absolutely dry instruments in the steriliser to avoid chalky deposits and/or water stains, for instance.

Procedure:

Steam sterilisation in a fractionated vacuum procedure at 134°C in a device in accordance with EN 13060:

1. Fractionated prevacuum (at least 3-fold)
2. Sterilisation temperature 134°C (-0/+3°C)
3. Hold time: at least 5 minutes (full cycle)
4. Drying time: at least 10 minutes

Please observe the standard 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.

The determination of the duration of the maintenance of sterility of the end product is the responsibility of the body that performed the final packaging (sterile barrier system or packaging system) in the dental practice. (See also "Packaging")

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 of the operating media used and of the manufacturers of the products and ensure that the maximum load of the products is observed.

Information from 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 processing 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.

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⚠ 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

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

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

Alternative:

Dry disposal
Collect the medicinal products (dry disposal) after appropriate pre-treatment or after patient treatment

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

1. Deposit the instruments
   in suitable collection containers, e.g. lockable plastic boxes.

   Carefully deposit the instruments (do not throw in), if necessary using instrument tongs.

   Attention must be paid to the appropriate personal protective equipment (e.g. protection of the hands, eye and mouth/nose).

   Avoid long processing times (recommendation: the 6-hour waiting time rule should not be exceeded; observe the manufacturer's instructions).

2. Sort out waste
   in sufficiently resistant, leak-tight and, if necessary, moisture-resistant waste bags.

Preparation for decontamination

Please also observe the instructions for system boxes commonly applied in your practice.

The processing of our system box takes place with the lid **open.**

HAHNENKRATT system boxes are not subject to any other particular requirements.

Cleaning and disinfection

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

Standardised 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 insert suitable for system boxes

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

WDD procedure:

1. Place the **opened** system box in a suitable insert.
2. Fill the 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 and cavities (drill holes) 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 defects/damage.

Packaging

Suitable individual packaging in a sterilisation wrap as per EN ISO 11607-1. The packaging must be adequately sized, so that the sealing is not under tension. Sterile barrier systems must be checked for intactness prior to use. If the sterile barrier system is damaged, the packaged product must be re-processed.

Validated sterilisation in the autoclave (moist heat)

Equipment: Steam steriliser, as per 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 (-0/+3°C)
3. Hold time: at least 5 minutes (full cycle)
4. Drying time: at least 10 minutes

Please observe the standard 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.

The determination of the duration of the maintenance of sterility of the end product is the responsibility of the body that performed the final packaging (sterile barrier system or packaging system) in the dental practice. (See also "Packaging")

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 of the operating media used and of the manufacturers of the products and ensure that the maximum load of the products is observed.

Information from 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 processing of medicinal products applicable in your country. Information is available at www.rki.de, for example.

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