PROCESSING OF PRODUCTS IN LINE WITH DIN EN ISO 17664/AAMI ST81

1. GENERAL PRINCIPLES

Endodontic instruments are to be used only in a clinical or hospital environment, following good dental practice, by qualified dental professionals such as general practitioners as well as Endo specialists (Endodontist) and Dental Assistants.

Please always inspect the packaging before each use to see that sterile packaging is undamaged. Do not use the instruments if the packaging is damaged.

All instruments that are intended for re-use must be cleaned, disinfected and sterilized prior to each use; this applies the first time instruments supplied in a non-sterile condition are used, and to instruments delivered in a sterile condition that are intended for re-use. Thorough cleaning and disinfection are essential prerequisites for effective sterilization.

As part of your responsibility for the sterility of instruments, always make sure that only validated methods for cleaning/ disinfection and sterilization are used, that devices (washer-disinfector, thermal disinfector or sterilizer) are regularly serviced and inspected, and that the validated parameters are maintained during each cycle. For your own safety, always wear protective gloves, glasses and a mask when handling contaminated instruments.

In addition, always observe all applicable national legal regulations (KRINKO/ RKI/BfArM Processing recommendations) and regulations on hygiene relating to your practice or the hospital. This applies in particular to the guidelines regarding prion inactivation (does not apply to the USA).

Disclaimer: The instructions for processing products prior to use/re-use herein have been validated. Users are solely responsible for any deviation from these instructions, and/or the use of alternative methods for processing. The Manufacturer accepts no liability for damage, injury, or any legal responsibility incurred directly or indirectly by the user due to a deviation from the instructions for use set forth below. The user shall observe safe and lawful practices including, but not limited to, those set forth in this document.

2. LIMITATIONS AND RESTRICTIONS ON PROCESSING

2.1. Re-use

Instruments (only reusable instruments) can be re-used several times – with due care and if they are not damaged and contaminated (see “Table 1”). Each re-use or application of non-validated methods is the sole responsibility of the user.

Certain applications may cause the instruments to prematurely reach the end of their useful life. The maximum number of processing cycles will not always be reached.

All liability is disclaimed for failure to follow these instructions or use of non-validated methods for the re-use of instruments.

Please always ensure that sterile packaging/wrapping is undamaged. Do not use the instruments if the packaging is damaged.

For shaping extremely curved canals it is safer to use the file only to shape one canal in order to reduce the risk of breakage. Pay attention to the following good practices:

- Use a new file and discard it after the canal has been treated (single canal use).
- Use manual instead of rotary files.
- Use small size, flexible or/and NiTi files (this will also enable canal transportation to be avoided).

- Visually inspect the active part for all the defects listed in the former paragraph during use.
- Avoid the standard continuous rotational reaming motion; instead use small angular motions, such as the filing motion, oscillating “watch winding” motion, or balanced force technique, in order to limit the amount of rotational bending fatigue the instruments are subject to, and improve their expected life.

2.2. Overview

Processing prior each use (for reusable products)

Table 1

Product designation	Material	Special/additional procedure			Packaging for sterilization	Maximum number of processing cycles *	Notes
		Pre-treatment	Manual cleaning/ disinfection	Automated cleaning/ disinfection			
NiTi Finger Spreader, NiTi K-File	NiTi, silicone rubber	Procedure A	Procedure A in box with mini step module	Procedure A in box with mini step module	MiniBox with step module with autoclave paper and single-use sterilization packaging	8	Cleaned and undamaged instruments can be used up to eight times depending on the degree of wear.
Reamer, K-File, C-File, Hedstrom File, Finger Spreader, Finger Plugger	Stainless steel, silicone rubber (only for instruments with stopper)	Procedure A	Procedure A in box with mini step module	Procedure A in box with mini step module	MiniBox with step module with autoclave paper and single-use sterilization packaging	8	Cleaned and undamaged instruments can be used up to eight times depending on the degree of wear.
Gates, Peeso	Stainless steel	Procedure A	Procedure A in box with mini step module	Procedure A in box with mini step module	MiniBox with step module with autoclave paper and single-use sterilization packaging	8	Cleaned and undamaged instruments can be used up to eight times depending on the degree of wear.

Processing prior each use (for single use products)
Table 2

Instrument/product	Material	Special notes on cleaning/ sterilization	Possible damage/risks if maintenance instructions are not followed
Barbed broaches	Stainless steel and temperature resistant plastic	Instruments marked as “not sterile” only: Singular sterilization before use.	Complete removal of pulpal tissue remnants from the barbs cannot be guaranteed.
Paper points	Paper	Delivered sterile. Processing not permitted.	Risk of contamination, deformation, loss of absorbance.
Gutta-percha points, Obturators	Gutta-percha, zinc oxide	• Immerse the obturation devices in 5.25% NaOCl for 1 to 5 minutes at ambient temperature. • Remove all the bubbles from the surface of the obturation devices. • Gently wipe the obturation devices with sterile gauze moistened with 70% isopropyl alcohol. • Let the obturation devices air dry.	• Risk of contamination, deformation, lower adhesion of sealer, etc. • Do not use disinfecting solutions containing Phenol or any products which are not compatible with the treated filling material.

2.3. Important Information on material resistance

When selecting cleaning and disinfecting agents, make sure that they do not contain any of the following substances:

- Phenol;
- Strong acids (pH <6) or strong alkalis (pH >8); neutral enzymatic cleaning agent recommended;
- Aldehydes;
- Anti-corrosive substances (especially di- or triethanolamine);
- Oxidants (hydrogen peroxide, sodium hypochlorite over 5% strength);
- NiTi instruments may only be placed in oxidants (< 5% strength sodium hypochlorite) for a maximum of 5 minutes;
- Solvents;
- Oils.

WARNING
Never clean the instruments, boxes, modules or the interim stand with metal brushes or wire wool.

- Never subject any instruments, boxes, modules or the interim stand to temperatures above 142 °C (288 °F). It is particularly important to ensure that the products to be sterilized are not stored too close to the walls or floor of the steam sterilizer (risk of excessive temperature and deformation).
- The blue foam insert for the stand must only be used once and used blue foam inserts must not be either cleaned/ disinfected or sterilized.

3. CLEANING AND DISINFECTING AGENTS

The following must be taken into account when selecting cleaning and disinfecting agents:

- They must be suitable for cleaning and disinfecting instruments made from metal and plastic;
- The disinfecting agent must be aldehyde-free (Cidex OPA is permitted due to its special recipe);
- It must be compatible with the instruments (see section “2.3. Important Information on material resistance”);
- A disinfecting agent with verified effectiveness (VAH/DGHM approval, FDA clearance or CE mark) must be used and this must be compatible with the cleaning agent used;
- If a thermal disinfection process is not used, a suitable disinfecting agent with verified effectiveness (VAH/DGHM approval, FDA clearance or CE mark) must also be used and this must be compatible with the cleaning agent used;
- Neutralization must not be necessary (cleaning agent);
- The cleaning agent, if applicable, must be suitable for ultrasonic cleaning (no foaming);
- Combined cleaning agents/disinfecting agents must not be used.

The concentrations, temperatures and contact times specified by the manufacturer of the cleaning agent and disinfecting agent as well as the minimum specifications for subsequent rinsing must be strictly adhered to. Rinse aids must not be used.

Only use freshly prepared solutions and low-germ (< 10 CFU/ml) water; tap water that is particularly hard (≥ 14 °dH) is not suitable for this (risk of lime residue).

4. INITIAL TREATMENT AT THE POINT OF USE

We recommend an automated procedure to clean and disinfect the instruments (washer-disinfector). A manual method should only be used if it is not possible to use an automated method, as it is less effective and demonstrates lower reproducibility. Manual cleaning and disinfection is less effective in direct comparison to the automated method. However, it is effective according to the requirements for a processed instrument. All methods are validated and therefore they are efficient and safe for the processing of instruments.

The pre-treatment process should be performed on used instruments in every case. We recommend to use the automated method for new non-sterile instruments. If the manual method is used, the new stopper needs to be removed and processed separately.

Pre-treatment at the place of use

Contaminants (particularly pulp and dentine remnants) must be removed immediately after the instrument has been used on a patient (within maximum 2 hours). All further steps in the preparation process must be performed on the same day.

The following procedures must be used to ensure that no contamination can dry on the instruments, and to make subsequent preparation more effective:

Table 3

Procedure A: Instruments that fit in the interim stand (see “Table 1”)	Procedure B: Instruments that do not fit in the interim stand (see “Table 1”)	Procedure C: Boxes and modules (see “Table 1”)
• A prepared interim stand with a new foam disc must be used for each patient. The interim stand must be filled at least two thirds of the way with disinfecting agent. • Place in the interim stand prior to predisinfection/cleaning and for transport (minimum storage time according to the disinfecting agent manufacturer’s instructions for use: Max. two hours).	• Place in a pan containing disinfecting agent within two hours (minimum storage time according to the disinfecting agent manufacturer’s instructions for use: Max. two hours) and brush at both the start and end of pre-treatment. • The pan is also used to transport the instruments.	• Within two hours, clean to remove contamination under flowing water for at least 3 x 1 min. on the outside and particularly on the inside. • Then place in a pan (not together with the instruments). • The pan is also used to transport the boxes and modules.

Please note that the disinfecting agent used during pre-treatment is for personal protection only and is not a substitute for the disinfection stage required after cleaning.

WARNING
Under no circumstances may instruments that have already come into contact with disinfecting agent be used to treat a patient again.

5. PREPARATION BEFORE CLEANING

Table 4

Procedure A: Instruments that fit in the interim stand (see “Table 1”)	Procedure B: Instruments that do not fit in the interim stand (see “Table 1”)	Procedure C: Boxes and modules (see “Table 1”)
• Remove the stopper from the instrument (if present, see “Table 1”) and dispose of the used stopper. • Then clean to remove contamination under flowing water for at least 3 x 1 minute; to remove contamination manually, use a soft, clean brush or soft, clean cloth that is only used for this purpose; never use metal brushes or wire wool.	• Clean to remove contamination under flowing water for at least 3 x 1 minute; to remove contamination manually, use a soft, clean brush or soft, clean cloth that is only used for this purpose; never use metal brushes or wire wool.	• Place in a pan containing cleaning agent for the prescribed contact time (but no less than 15 minutes) and brush at both the start and end of the contact time on the outside and particularly on the inside for at least one minute each (using a soft, clean brush; never use metal brushes or wire wool).
• Check that no visible contamination or remnants remain and repeat the pre-cleaning process if necessary.		

6. CLEANING AND DISINFECTION

Automated cleaning/disinfection (washer-disinfector)

The following must be taken into account when selecting a washer-disinfector:

- The effectiveness of the washer-disinfector must have been verified (DGHM approval, FDA clearance or CE mark according to EN ISO 15883);
- Where possible, a tested thermal disinfection program must be used (A0 value >=3000 or at least five minutes at 90 °C, or for older equipment at least 10 min. at 93 °C).

Processing of Patterson® Products

WARNING
In the case of chemical disinfection, there is a risk of disinfecting agent residues remaining on the instruments.

- The program used must be suitable for the instruments and include the prescribed rinsing cycles;
- Only sterile or low-germ (< 10 CFU/ml) and low-endotoxin (< 0.25 EU/ml) water (ideally highly purified water HPW) must be used for subsequent rinsing;
- The washer-disinfector must be regularly maintained and inspected.

Table 5

	Procedure A: Instruments that fit in the interim stand (see “Table 1”)	Procedure B: Instruments that do not fit in the interim stand (see “Table 1”)	Procedure C: Boxes and modules (see “Table 1”)
1.	• If present (see “Table 1”): Fit new stoppers to the precleaned instruments or keep the stopper on the new non-sterile instrument. • Sort the instruments into the endo modules. • Place the endo module in the black upper section (manual instruments, “Figure 1”) or the blue lower section (nickel titanium instruments, “Figure 2”) of the box and close it (click into place).  Figure 1  Figure 2 **NOTE** Preparation in the socket module is not permitted. • Insert the box horizontally into the washer-disinfector.	• Place in a sufficiently large mesh basket (Minifix measuring gauge: Small parts basket) and insert into the washer-disinfector, ensuring that the instruments are not touching.	• Place in a sufficiently large mesh basket with the openings facing down and insert into the washer-disinfector (using a securing net if necessary), ensuring that the instruments are not touching.
2.	• Start the program.		
3.	• After the program has finished, remove the box from the washer-disinfector.	• After the program has finished, remove the instruments from the washer-disinfector.	
4.	• Check and package the instruments as soon as possible after removing them (see section “7. Inspection and maintenance” and “8. Packaging”), after leaving them to dry further in a clean place if necessary.		

An independent, accredited, recognized test laboratory has demonstrated the intrinsic suitability of the instruments for effective automated cleaning and disinfection using the G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the Neodisher Medizym cleaning agent (Dr. Weigert, Hamburg). The laboratory used program D-V-MEDIZYM (based on the program DES-VAR-TD (Miele) under worst-case conditions) according to the procedure described above to demonstrate this effectiveness. The Cidex OPA disinfecting agent and the Cidezyme cleaning agent (both Johnson & Johnson GmbH, Norderstedt) were used for pre-treatment. Cleaning and disinfection validation were performed under worst-case conditions (low temperature, low concentration of agent, short soaking time and no drying).

Manual cleaning and disinfection

Table 6

	Procedure A: Instruments that fit in the interim stand (see “Table 1”)	Procedure B: Instruments that do not fit in the interim stand (see “Table 1”)	Procedure C: Boxes and modules (see “Table 1”)
1.	• Sort the instruments, without stoppers, into the endo modules. • Place the endo module in the black upper section (manual instruments, “Figure 3”) or the blue lower section (nickel titanium instruments, “Figure 4”) of the box and close it (click into place).  Figure 3  Figure 4 ☞ **NOTE** Preparation in the socket module is not permitted. • If present (see “Table 1”): Place new stoppers in a small parts basket with a sufficiently small mesh size. • Insert the box horizontally and, if present, the small parts basket with the new stoppers into the cleaning bath for the prescribed contact time, ensuring that the instruments are sufficiently covered. • Then remove the box and, if present, the small parts basket with the stoppers from the cleaning bath and rinse thoroughly with water for at least 3 x 1 min.	• Place the instruments in the cleaning bath in a sufficiently large mesh basket for the prescribed contact time, ensuring that the instruments are sufficiently covered but are not touching. • Then remove the mesh basket from the cleaning bath and rinse thoroughly with water for at least 3 x 1 min.	• Place in a sufficiently large mesh basket with the openings facing down and insert into the ultrasonic bath filled with a sufficient amount of cleaning solution for the prescribed contact time (but no less than five minutes) and brush on the outside and particularly on the inside for at least one minute each (using a soft, clean brush; never use metal brushes or wire wool). • Then check that the instruments are not touching and activate the ultrasound for the prescribed contact time (but no less than five minutes). • Then remove the mesh basket from the cleaning bath and rinse thoroughly with water for at least 3 x 1 min.
2	• Insert the box horizontally and, if present, the small parts basket with the new stoppers into the disinfection bath for the prescribed contact time, ensuring that the instruments are sufficiently covered. • Then remove the box and, if present, the small parts basket with the stoppers from the disinfection bath and rinse thoroughly with water for at least 5 x 1 min. • Dry the box and, if present, the small parts basket with the stoppers by blowing them with oil-free, filtered compressed air (or medical compressed air from a can) and then leaving them to dry further in a clean place. • Check and package the instruments as soon as possible (see section “7. Inspection and maintenance” and “8. Packaging”) and, if present (see “Table 1”), fit stoppers to the instruments.	• Place in the disinfection bath in a sufficiently large mesh basket for the prescribed contact time, ensuring that the instruments are sufficiently covered but are not touching. • Then remove the mesh basket from the disinfection bath and rinse thoroughly with water for at least 5 x 1 min. • Dry the instruments by blowing them with oil-free, filtered compressed air (or medical compressed air from a can) and then leaving them to dry further in a clean place. • Check and package the instruments as soon as possible (see section “7. Inspection and maintenance” and “8. Packaging”).	• Place in the disinfection bath in a sufficiently large mesh basket for the prescribed contact time, ensuring that the instruments are sufficiently covered but are not touching. • Then remove from the disinfection bath and rinse thoroughly with water for at least 5 x 1 min. • Dry by blowing them with oil-free, filtered compressed air (or medical compressed air from a can) and then leaving them to dry further in a clean place. • Check and package as soon as possible (see section “7. Inspection and maintenance” and “8. Packaging”).

An independent, accredited, recognized test laboratory has demonstrated the intrinsic suitability of the instruments for effective manual cleaning and disinfection using the cleaning agent Cidezyme/Enzol and disinfecting agent Cidex OPA (Johnson & Johnson GmbH, Norderstedt (Germany)). The laboratory used the procedure described above to demonstrate this. The Cidex OPA disinfecting agent and the Cidezyme cleaning agent (both Johnson & Johnson GmbH, Norderstedt) were used for pre-treatment.

7. INSPECTION AND MAINTENANCE

Open the boxes and remove the modules. Check all instruments, modules and boxes after cleaning/disinfection. Defective instruments, boxes and modules should be discarded immediately.

These defects include:

- Plastic deformation (e.g., caused by an excessively high temperature during sterilization);
- Breakage;
- Loss of color coding or marking;
- Bent instrument;
- Untwisted threads;
- Damaged cutting surfaces;
- Dull cutting blades;
- Missing size marking;
- Corrosion.

Numerical restrictions on re-use are listed under “Maximum number of processing cycles”. Instruments that are still contaminated must be cleaned and disinfected again.

WARNING
Instrument lubricants must not be used.

8. PACKAGING

Place the module in the lower section of the black sterilization tray and close it with the matching cover. Then package the sterilization trays and instruments that do not fit in the interim stand (see “Table 1”) into disposable sterilization pouches (disposable packaging) that meet the following requirements:

- Compliance with DIN EN 11607/ANSI AAMI ISO 11607;
- Suitable for steam sterilization (withstands temperatures of up to 142 °C (288 °F) or more, sufficient vapor permeability).

WARNING
Sterilization in the sterilization trays without additional packaging is not permitted. The autoclave paper in the boxes is for added safety only.

9. STERILIZATION

Only use the sterilization methods listed below; other sterilization methods are not permitted.

Steam sterilization

- Fractionated vacuum/pre-vacuum method (at least three vacuum cycles) or gravity displacement method[1] with sufficient product drying[2];

- Steam sterilizer in accordance with DIN EN 13060 or DIN EN 285, ANSI AAMI ST79;
- Validated in accordance with DIN EN ISO 17665 (valid IQ and OQ plus product-specific performance qualification (PQ));
- The maximum sterilization temperature of 138 °C (280 °F) must not be exceeded; the maximum sterilization temperature includes a tolerance according to DIN EN ISO 17665;
- See “Table 7 (outside the USA)” for outside the USA, “Table 8 (USA)” for the USA only.

Table 7 (outside the USA)

Sterilization procedure	Sterilization temperature	Minimum sterilization time Exposure time at sterilization temperature
Fractionated vacuum/pre-vacuum method	134 °C (273 °F)	3 minutes[3]
	121 °C (250 °F)	20 minutes
Gravity method[4]	134 °C (273 °F)	15 minutes
	121 °C (250 °F)	60 minutes

Table 8 (USA)

Sterilization procedure	Sterilization temperature	Minimum sterilization time Exposure time at sterilization temperature	Minimum drying time[2]
Fractionated vacuum/pre-vacuum method	132 °C (270 °F)	4 minutes	20 minutes
	Not applicable at 121 °C (250 °F)		
Gravity method	134 °C (273 °F)	15 minutes	20 minutes
	121 °C (250 °F)	60 minutes	20 minutes

[1] The less effective gravity method should only be used if the fractionated vacuum method is not available. The gravity method is less effective in direct comparison to the fractionated vacuum method. However, it is effective according to the requirements for a processed instrument. All methods are validated and therefore they are efficient and safe for the processing of instruments.
[2] The drying time that is actually required depends directly on parameters that are the sole responsibility of the user (loading configuration, how many items are loaded and how closely together they are loaded, condition of the sterilizer, etc.) and must therefore be established by the user. However, the drying time must never be less than 20 minutes.
[3] Or 18 min. (prion inactivation).
[4] Gravity method is not applicable for processing within the European Union.

Rapid sterilization method (USA: Immediate-use steam sterilization) and the sterilization method of unpackaged instruments (USA: Unwrapped sterilization) are not permitted.

Dry heat sterilization, radiation sterilization and sterilization using formaldehyde, ethylene oxide or plasma are also not permitted.

An independent, accredited, recognized test laboratory demonstrated the instruments' intrinsic suitability for effective steam sterilization using the HST 6x6x6 steam sterilizer (Zirbus Technology GmbH, Bad Grund) together with the fractionated vacuum method and the gravity method. The laboratory used typical conditions found in clinics and dental practices, as well as the procedure described above, to demonstrate this.

10. STORAGE AND TRANSPORT

After sterilization, devices must be stored in the sterilization packaging and kept dry and dust-free. In case of damage to the packaging during storage or transport, the processing shall be repeated. Check the instructions for use given by the pouch manufacturer to determine the shelf life of the sterile packaging.

11. DISPOSAL

Instruments shall be disposed of according to local regulations for the safe disposal of sharp and contaminated devices.

12. ADDITIONAL INFORMATION

- Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.
- Sterility cannot be guaranteed if packaging is open, damaged or wet.

Manufactured for:
Fabriqué pour :

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