Instructions for Use and Re-Processing of VDW Products

VW000304 Rev. 7 / 28.03.17

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General principles

All instruments must be cleaned, disinfected and sterilised prior to each use; this applies the first time instruments supplied in a non-sterile condition are used, to instruments delivered in a sterile condition that are intended for repeated use, and to damaged or opened sterile packaging. Thorough cleaning and disinfection are essential prerequisites for effective sterilisation.

As part of your responsibility for instruments sterility, always make sure that only validated methods for cleaning/disinfection and sterilisation are used, that devices (washer-disinfector, thermal disinfector or steriliser) are regularly serviced and inspected and that the validated parameters are maintained with 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 (e.g. KRINKO/RKI/BfArM Re-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).

Cleaning and disinfection

Basic Principles
We recommend an automated procedure to clean and disinfect the instruments (washer-disinfector). A manual method- including the use of an ultrasonic bath, should only be used if it is not possible to use an automated method, as it is less effective and demonstrates a lower reproducibility. The pre-treatment process should be performed in every case.

Pre-Treatment at the place of use
Cross contamination (particularly pulp and dentine remnants) must be removed immediately after the instrument has been used on a patient (within maximum 2 hrs).

The following procedures must be used to ensure that any contamination on the instruments cannot dry on and to make subsequent preparation more effective:

Procedure A: **Instruments that fit in the interim stand (see Table 3)**	Procedure B: Instruments that do not fit in the interim stand (see Table 3)	Procedure C: Boxes and modules (see Table 3)
• Place in the interim stand prior to pre-disinfection/ cleaning and for transport (minimum storage time according to the disinfecting agent manufacturer's directions for use: Max. two hours). • 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 a pan containing disinfecting agent within two hours (minimum storage time according to the disinfecting agent manufacturer's directions 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 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.
The following must be taken into account when selecting a disinfecting agent: • It must be suitable for disinfecting instruments made from metal and plastic; • It must be aldehyde-free (Cidex OPA is permitted due to its special recipe); • Its effectiveness must have been verified (e.g. VAH/DGHM approval, FDA clearance or CE mark); • It must be compatible with the instruments (see section "Important notes on material resistance"). The concentration and minimum contact time specified by the disinfecting agent manufacturer must be strictly adhered to. Only use freshly prepared solutions and low-germ (< 10 CFU/ml) water (e.g. purified water (PW)). 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.		Use only low-germ (< 10 CFU/ml) water (e.g. purified water (PW)); tap water that is particularly hard (≥ 14 °dH) is not suitable for this (risk of lime residue).

All further steps in the preparation process must be performed on the same day.

Re-Processing in Line with DIN EN ISO 17664/AAMI ST81

Preparation prior to cleaning

Procedure A: **Instruments that fit in the interim stand (see Table 3)**	Procedure B: Instruments that do not fit in the interim stand (see Table 3)	Procedure C: Boxes and modules (see Table 3)
• Remove the stopper from the instrument (if present, see Table 3) and dispose of it. • Then clean to remove contamination under flowing water 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. • Check that no visible contamination or remnants remain, and repeat the pre-cleaning process if necessary.	• Clean to remove contamination under flowing water 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. • Check that no visible contamination or remnants remain, and repeat the pre-cleaning process if necessary.	• 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.
Use only low-germ (< 10 CFU/ml) water (e.g. purified water (PW)); tap water that is particularly hard (≥ 14 °dH) is not suitable for this (risk of lime residue).		The following must be taken into account when selecting a cleaning agent: • It must be suitable for cleaning instruments made from metal and plastic ; • It must be compatible with the instruments (see section “Important notes on material resistance”). The concentration and minimum contact time specified by the cleaning agent manufacturer must be strictly adhered to. Only use freshly prepared solutions and low-germ (< 10 CFU/ml) water (e.g. purified water (PW)); tap water that is particularly hard (≥ 14 °dH) is not suitable for this (risk of lime residue).

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 (e.g. 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).

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 (e.g. highly purified water HPW) must be used for subsequent rinsing;
- The washer-disinfector must be regularly maintained and inspected.

The following must be taken into account when selecting a cleaning agent:

- It must be suitable for cleaning the instruments;
- If a thermal disinfection process is not used, a suitable disinfecting agent with verified effectiveness (e.g. VAH/DGHM approval, FDA clearance or CE mark) must also be used and this must be compatible with the cleaning agent used;
- The chemicals used must be compatible with the instruments (see section “Important notes on material resistance”);
- Neutralisation must not be necessary.

The concentrations, temperatures and contact times specified by the manufacturer of the cleaning agent and, where applicable, disinfecting agent, must be strictly adhered to. Rinse aids must not be used.

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	Procedure A: **Instruments that fit in the interim stand (see Table 3)**	Procedure B: **Instruments that do not fit in the interim stand (see Table 3)**	Procedure C: **Boxes and modules (see Table 3)**
1.	• If present (see Table 3): Fit new stoppers to the pre-cleaned instruments. • Sort the instruments into the endo modules (step modules for manual instruments and FlexMaster/ Mtwo modules for nickel-titanium instruments). • 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 LavEndo box and close it (click into place).  Figure 1 Figure 2 Note: Preparation in the socket module is not permitted. • Insert the LavEndo box horizontally into the washer-disinfector.	• Place in a sufficiently large screen 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 screen 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 LavEndo 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 “Checks, maintenance and packaging”), after leaving them to dry further in a clean place if necessary.		

An independent, accredited, recognised (Section 15 (5) MPG) test laboratory demonstrated the instruments’ intrinsic suitability 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 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.

Manual cleaning and disinfection
The following must be taken into account when selecting a cleaning agent and disinfecting agent:

- They must be suitable for cleaning and disinfecting instruments;
- The cleaning agent, if applicable, must be suitable for ultrasonic cleaning (no foaming);
- A disinfecting agent with verified effectiveness (e.g. VAH/DGHM approval, FDA clearance or CE mark) must be used and this must be compatible with the cleaning agent used;
- The chemicals used must be compatible with the instruments (see section “Important notes on material resistance”).

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. Only use freshly prepared solutions, sterile or low-germ (< 10 CFU/ml) and low-endotoxin (< 0.25 EU/ml) water (e.g. highly purified water HPW).

Re-Processing in Line with DIN EN ISO 17664/AAMI ST81

	Procedure A: **Instruments that fit in the interim stand** **(see Table 3)**	Procedure B: **Instruments that do not fit in the interim stand** (see Table 3)	Procedure C: **Boxes and modules** (see Table 3)
1.	• Sort the instruments, without stoppers, into the endo modules (step modules for manual instruments and FlexMaster/Mtwo modules for nickel-titanium instruments). • 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 LavEndo box and close it (click into place).  Figure 3  Figure 4 Note: Preparation in the socket module is not permitted. • If present (see Table 3): Place new stoppers in a small parts basket with a sufficiently small mesh size. • Insert the LavEndo 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 (with ultrasound assistance if necessary). • Then remove the LavEndo box and, if present, the small parts basket with the stoppers from the cleaning bath and rinse thoroughly with water at least 3 x 1 min.	• Place the instruments in the cleaning bath in a sufficiently large screen basket for the prescribed contact time (with ultrasound assistance if necessary), ensuring that the instruments are sufficiently covered but are not touching. • Then remove the screen basket from the cleaning bath and rinse thoroughly with water at least 3 x 1 min.	• Place in a sufficiently large screen 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 screen basket from the cleaning bath and rinse thoroughly with water at least 3 x 1 min.
2.	• Insert the LavEndo 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 LavEndo box and, if present, the small parts basket with the stoppers from the disinfection bath and rinse thoroughly with water at least 5 x 1 min. • Dry the LavEndo box and, if present, the small parts basket with the stoppers by blowing them down fully 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 “Checks, maintenance and packaging”) and, if present (see Table 3), fit stoppers to the instruments.	• Place in the disinfection bath in a sufficiently large screen basket for the prescribed contact time, ensuring that the instruments are sufficiently covered but are not touching. • Then remove the screen basket from the disinfection bath and rinse thoroughly with water at least 5 x 1 min. • Dry the instruments by blowing them down fully 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 “Checks, maintenance and packaging”).	• Place in the disinfection bath in a sufficiently large screen 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 at least 5 x 1 min. • Dry by blowing them down fully 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 “Checks, maintenance and packaging”).

An independent, accredited, recognised (section 15 (5) MPG) test laboratory demonstrated the instruments' intrinsic suitability 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.

Inspection

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

These defects include:

- plastic deformation (e.g. caused by an excessively high temperature during sterilisation);
- bent instrument;
- untwisted threads;
- damaged cutting surfaces;
- dull cutting blades;
- missing size marking;
- corrosion;
- discolouration.

Numerical restrictions on reuse are listed under "Reusability". Instruments that are still contaminated must be cleaned and disinfected again.

Maintenance

Warning: Instrument lubricants must not be used.

Packing

Place the Step or FlexMaster/Mtwo module in the lower section of the black sterilisation tray (Figure 5) and close it with the matching cover. Then package the sterilisation trays and instruments that do not fit in the interim stand (see Table 3) into disposable sterilisation pouches (disposable packaging) that meets the following requirements:

- compliance with DIN EN 11607/ANSI AAMI ISO 11607;
- suitable for steam sterilisation (withstands temperatures of up to 142 °C (288 °F) or more, sufficient vapour permeability).

Figure 5

Warning: Sterilisation in the sterilisation trays without additional packaging is not permitted. The autoclave paper in the boxes is for added safety only.

Sterilisation

Use only the sterilization methods listed below; other sterilization methods are not permitted.

Steam sterilisation:

- Fractional vacuum/pre-vacuum method (at least three vacuum cycles) or gravity displacement method[1] with sufficient product drying[2];
- Steam steriliser 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));
- Maximum sterilisation temperature of 138 °C (280 °F) must not be exceeded; plus tolerance according to DIN EN ISO 17665;
- See Table 1 for outside the USA, Table 2 for the USA only.

Sterilisation procedure	Sterilisation temperature	Minimum sterilisation time Exposure time at sterilisation temperature
Fractionated vacuum/ pre-vacuum method	134°C (273°F)	3 minutes[3]
Fractionated vacuum/ pre-vacuum method	121°C (250°F)	20 minutes
Gravity method	134°C (273°F)	5 minutes
Gravity method	121°C (250°F)	60 minutes

Table 1 (outside the USA)

Sterilisation procedure	Sterilisation temperature	Minimum sterilisation time Exposure time at sterilisation temperature	Minimum drying time2
Fractionated vacuum/ pre-vacuum method	132°C (270 F)	4 minutes	20 minutes
Fractionated vacuum/ pre-vacuum method	Not applicable at 121°C (250°F)		
Gravity method	132°C (270°F)	15 minutes	20 minutes
Gravity method	121°C (250°F)	60 minutes	20 minutes

Table 2 (USA)

1. The less effective gravity method should only be used if the fractionated vacuum method is not available.

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 steriliser, 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).

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

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

An independent, accredited, recognised (Section 15 (5) MPG) test laboratory demonstrated the instruments' intrinsic suitability for effective steam sterilisation using the HST 6x6x6 steam steriliser (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.

Storage

After sterilisation, instruments must be stored in the sterilisation packaging and kept dry and dust-free.

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 sterilised are not stored too close to the walls or floor of the steam steriliser (risk of excessive temperature and deformation).

The blue foam insert for the interim stand must only be used once and must neither be cleaned/disinfected nor sterilised.

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Re-use

Instruments can be reused several times – with proper care and if they are not damaged and contaminated;. See Table 3 below. 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 preparations 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.

Disposal

For proper disposal, always observe national laws and recommendations of the authorities.

Overview

Product designation	Material	Special/additional proced	
		Pre-treatment	Manual cleaning/ disinfection
FlexMaster	NiTi, silicone rubber	Procedure A after removing and disposing of the stoppers	Procedure A in LavEndo box with FlexMaster module
Mtwo	NiTi, silicone rubber	Procedure A after removing and disposing of the stoppers	Procedure A in LavEndo box with Mtwo module
NiTi Finger Spreader, NiTi K-File	NiTi, silicone rubber	Procedure A after removing and disposing of the stoppers	Procedure A in LavEndo box with mini step module
K-Reamer, K-File, C-File, Hedstroem File (up to and including a size of 70), Flexicut Files, Finger Spreader, Finger Plugger	Stainless steel, silicone rubber	Procedure A after removing and disposing of the stoppers	Procedure A in LavEndo box with mini step module
K-Reamer, K-File, Hedstroem File (size 80 and above), K-Reamer, Hedstroem File for contra-angle	Stainless steel	Procedure A	Procedure A in LavEndo box with mini step module
Gates, Peeso, B-Reamer, root filler, Beutelrock enlarger	Stainless steel	Procedure A	Procedure A in LavEndo box with mini step module
MC instruments	Stainless steel, temperature-resistant plastic	Procedure B	Procedure B in screen tray
Machtou Handplugger	Stainless steel or NiTi	Procedure B	Procedure B in screen tray
Minifix measuring gauge	Temperature-resistant plastic	Procedure B	Procedure B in screen tray
Endo boxes, endo modules, LavEndo box (if preparation must take place separately from instruments, particularly in the case of heavy contamination)	Temperature-resistant plastic	Procedure C	Procedure C
Interim stand	Temperature-resistant plastic	Procedure B after removing and disposing of the foam disc	Procedure B, storage in screen tray
Silicone stopper	Silicone rubber	Procedure A	Procedure A in small parts basket

Table 3

lure for		Packaging for sterilisation	Reusability	Recommended classification according to RKI/BfArM/KRINKO directive (Germany only, intended use)	Notes
	Automated cleaning/ disinfection				
	Procedure A in LavEndo box with FlexMaster module	FlexMaster SystemBox/ AccessoryBox/CombiBox with autoclave paper and single-use sterilisation packaging	8	Critical B	Cleaned and undamaged instruments can be used up to eight times, depending on the curvature of the canal. Please observe the product-specific directions for use. (See also www.vdw-dental.com)
	Procedure A in LavEndo box with Mtwo module	Mtwo SystemBox with autoclave paper and single-use sterilisation packaging	8	Critical B	Cleaned and undamaged instruments can be used up to eight times, depending on the curvature of the canal. Please observe the product-specific user manual. (See also www.vdw-dental.com)
	Procedure A in LavEndo box with mini step module	MiniBox, Basic Box, SemiBox with step module with autoclave paper and single-use sterilisation packaging	8	Critical B	Depending on degree of wear.
	Procedure A in LavEndo box with mini step module	MiniBox, Basic Box, SemiBox with step module with autoclave paper and single-use sterilisation packaging	8	Critical B	Cleaned and undamaged instruments can be used up to eight times.
	Procedure A, LavEndo box with mini step module	MiniBox, Basic Box, SemiBox with step module with autoclave paper and single-use sterilisation packaging	8	Critical A	Cleaned and undamaged instruments can be used up to eight times.
	Procedure A in LavEndo box with mini step module	MiniBox, Basic Box, SemiBox with step module with autoclave paper and single-use sterilisation packaging	8	Critical A	Cleaned and undamaged instruments can be used up to eight times.
	Procedure B in screen tray	Single-use sterilisation packaging	8	Critical A	Cleaned and undamaged instruments can be used up to eight times.
	Procedure B in screen tray	Single-use sterilisation packaging	8	Critical A	Depending on degree of wear.
	Procedure B in small parts box	Single-use sterilisation packaging	50	-	If the specified sterilisation temperature and time are exceeded, this may result in plastic deformation.
	Procedure C	Single-use sterilisation packaging	50	-	If the specified sterilisation temperature and time are exceeded, this may result in plastic cracks or deformation. Disassemble during pre-treatment, do not clean or disinfect when assembled.
	Procedure B, storage in screen tray	Single-use sterilisation packaging	50	-	If the specified sterilisation temperature and time are exceeded, this may result in plastic cracks or deformation. Disassemble and dispose of the foam disc during pre-treatment, do not clean or disinfect when assembled. The new foam disc can be sterilised at the same time.
	Procedure A, fitted to instrument	Fitted to instrument	1	See corresponding instrument.	The stopper used must be removed during pre-treatment and replaced with a new stopper either before or after automated cleaning/disinfection.

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Products for single use only:

Instrument/product	Material	Special notes on cleaning/sterilisation	Reusability	Possible damage/risks if maintenance instructions are not followed
RECIPROC instruments	Please consult respective Directions for Use (see also www.RECIPROC.com).			
Barbed broaches	Stainless steel and temperature-resistant plastic	Instruments marked as “not sterile” only: One-off sterilisation before use. No cleaning/disinfection permitted. Observe the instructions from the section “Packaging” onwards.	For single use only	Proper removal of pulpal tissue remnants from the barbs cannot be guaranteed.
Foam discs for interim stand	Foam	Reprocessing not permitted. Foam disc autoclavable once before single use.	For single use only	Disintegration of the foam if used more than once; risk of contamination from dried-on residues.
Silver points	Silver	Please consult respective Directions for Use (see also www.RECIPROC.com)	For single use only	Risk of contamination, deformation, attached sealer remnants etc.
Paper points	Paper		For single use only	Risk of contamination, deformation, loss of absorbance.
Guttapercha points	Guttapercha, zinc oxide and barium sulphate	Cold disinfection, e.g. in med. alcohol	For single use only	Risk of contamination, deformation, adhesion of sealer etc.
Silicone stopper	Silicone rubber	The stopper used must be removed during pre-treatment and replaced with a new stopper.	For single use only	Proper cleaning of hole cannot be guaranteed.
EDDY	Please consult respective Directions for Use (see also www.RECIPROC.com).			Risk of breakage if used incorrectly; sterilisation alters the material characteristics, thereby discolouring the instrument and making it porous.

For the protection of the patient's airways we recommend to always work with a rubber dam!

1. Hand instruments

Indication for use: Root canal treatment
Contraindication: None known (short-term application)

Manufacturer: VDW GmbH

Instrument/product	Application
K-Reamer	Pushing/rotating motion (/reaming motion), max. 90° clockwise.
K-Files Flexicut Files C-PILOT Files	Filing motion, max. 45° clockwise. Standard preparation methods, e.g. step back, step down, standardised method, balanced force, etc.
NiTi K-Files	NiTi K-Files are for manual use only. Pushing and pulling motion without rotation. Rotating motion would cause the sharp blades to block.
Hedstroem Files	Pushing and pulling motion without rotation. Rotating motion would cause the sharp blades to block. If the canal was enlarged with K-reamers, Flexicut or K-files, the following Hedstroem file should be one size smaller or equal.
MC instruments	Pushing and pulling motion without rotation.
Barbed broaches (Exstirpation needles)	Push into the canal and pull out following a rotating motion of approx. 180º.
Finger Spreader NiTi Finger Spreader	Lateral condensation of gutta-percha points. The spreader is placed between the points and pushed carefully in apical direction.
Finger Plugger Machtou Plugger	Vertical condensation of gutta-percha points. Carefully condense the gutta-percha points with the blunt instrument tip.

2. Instruments for use in the contra-angle

Indication for use: Root canal treatment
Contraindication: None known (short-term application)

Manufacturer: VDW GmbH

Pull on the instrument to check if it is firmly locked in the contra-angle. Note the instructions in the manufacturerer's manual.

Instrument/product	Application	
Mtwo, FlexMaster	Please consult respective Directions for Use. (also available at www.vdw-dental.com)	
RECIPROC	Please consult respective Directions for Use. (also available at www.vdw-dental.com)	
K-Reamer	Green contra-angle, max. 800 rpm.	
Hedstroem files	In yellow contra-angle only with 1/4 rotation, 450 – 800 rpm.	
Beutelrock reamer	Green contra-angle, 450-800 rpm. High risk of perforation, therefore only to be used for the straight part of the canal. Green contra-angle, to be used only for the straight part of the canal, due to high perforation risk.	
Beutelrock enlarger	Green contra-angle, 450-800 rpm. Use only to clear the canal access and to enlarge the coronal part.	
Peeso enlarger	Green contra-angle, 800-1,200 rpm To prepare the root canal access, to enlarge the coronal section and to create recesses for placing root posts.	
Gates enlarger	Green contra-angle, 800-1,200 rpm. To prepare the coronal part of the root canal before using files or K-reamers.	
Root canal filler type "L"	Green contra-angle. With the handpiece shut off, submerge root filler in filling material, insert root filler close to the apex, and with max. 300 - 600 rpm rotate filling material into the canal whilst slowly withdrawing the instrument from the canal.	
Minifix measuring gauge	Indication: adjustment of the working lenth of endo instruments, gutta-percha and paper points. Contra-indications: none known. Instruments: Place the stopper in the right-hand grove and adjust length by using the scale. Gutta-percha points: Measure the length in the left recess and mark with notches on the point using tweezers. Paper points: Measure the length in the left recess and mark with lateral creases.	

These instructions are available in several languages upon request.

Note:

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