

Instructions for Use and Re-Processing of VDW Products



General Principles

All instruments must be cleaned, disinfected and sterilised prior to each use. This also applies to the first use of instruments supplied non-sterile as well as in cases where the sterile packaging has been damaged or opened. Thorough cleaning and disinfection are essential prerequisites for effective sterilisation. For any special instructions with respect to cleaning/sterilisation, consult the respective instructions for use. In addition, the operating instructions of the devices used in your practice must be followed.

As part of your responsibility for instrument sterility, always ensure that only validated methods for cleaning/disinfection and sterilisation are used, that devices (disinfector, steriliser) are regularly serviced and inspected and that the validated parameters are maintained with each cycle.

In addition, always observe all applicable legal regulations and regulations on hygiene relating to your practice or the hospital as well as the requirements of the Robert Koch Institute. This applies in particular to the guidelines regarding effective prior inactivation.

For your own safety, always wear protective gloves, glasses and a mask when handling contaminated instruments.

Cleaning and Disinfection

Basic Principles

We recommend a mechanical method (disinfector) to clean and disinfect the instruments. A manual method – including the ultrasonic bath – should only be used if a mechanical method is not available, as it is less effective and demonstrates a lower reproducibility. The pre-treatment process should be performed in every case.

Pre-Treatment

Pulp and dentin residues must be removed immediately after the instrument has been used on a patient (within maximum 2 hrs). Do not let residue or any form of contamination dry: Risk of contamination due to residue! After the instruments have been used on patients, place the instruments for cleaning, pre-disinfection and interim storage directly into the interim stand filled with an appropriate cleaning and disinfecting solution (for max. 2 hrs). A clean interim stand with a new foam disk must be used for each patient.

Then clean the instruments under running water (at least 3 x 1 minute) or clean in Sekumatic FRK or any suitable disinfecting solution and check instrument for any signs of visible contamination. The disinfectant should be aldehyde-free (aldehyde fixes blood stains), tested for effectiveness (e.g. VAH/DGHM or FDA certification or CE mark), suitable for instrument disinfection and

compatible with the instruments (see chapter “Important Information on Material Resistance”).

Use only clean, soft brushes to manually remove contamination or a clean, soft cloth used only for this purpose. Do not use metal brushes or steel wool.

Please note that disinfectants used for pre-treatment are only for personal protection and do not replace disinfection when cleaning is completed.

Mechanical Cleaning/ Disinfection

– Thermo-Disinfection (Disinfector/CDU)

When purchasing a disinfector, always ensure:

- that its effectiveness has been tested (e.g. VAH/DGHM or FDA certification or CE mark according to DIN EN ISO 15883)
- that a tested programme for thermal disinfection is available (at least 10 min. at 93 °C or A-value >3000) (chemical disinfection might leave chemical residue on the instrument)
- that the programme for instrument disinfection is suitable and provides sufficient rinsing cycles
- that only sterile or low-germ (< 10 CFU/ml) and endotoxin-free water (< 0.25 EU/ml, e.g. high purity water HPW) is used and
- that the disinfector is regularly serviced and inspected.

When purchasing a cleaning agent system, always ensure:

- that it is suitable for cleaning instruments
- that you can use an additional disinfectant tested for effectiveness (e.g. VAH/ DGHM or FDA certification or CE mark) and compatible with the cleaning agent in case no thermal disinfection is foreseen, and
- that the chemicals used are compatible with the instruments (see chapter “Important Information on Material Resistance”).

The concentration rates indicated by the manufacturer of the cleaning agent/disinfectant must be observed.

Re-Processing in Line with DIN EN ISO 17664

Process:

1. Sort the pre-cleaned instruments into your endo module and place it into the LavEndo® box. Cleaning of loose instruments is not permitted.
2. Place the LavEndo® box into the disinfectant.
3. Start the programme.
4. When the programme has run, remove the LavEndo® box from the disinfectant.
5. After removal and, if necessary, additional drying, inspect pack and store the instruments as quickly as possible in a clean place (see chapter Inspection, Instrument Maintenance and Packing).

Instruments and products which cannot be cleaned in the LavEndo® box must be disassembled – if possible. Please also note that the instruments/products may not touch one another.

Manual Cleaning and Disinfection

When selecting the cleaning and disinfecting agents, you should ensure that

- they are suitable for cleaning or disinfecting instruments
- that the cleaning agent – if applicable – is suitable for ultrasonic cleaning (i.e. that no foam is formed)
- that a disinfectant with tested effectiveness is used (e.g. VAH/DGHM or FDA certification or CE mark) and that it is compatible with the cleaning agent
- that the chemicals used are compatible with the instruments (see chapter “Important Information on Material Resistance”).

Combined cleaning/disinfectant agents should only be used when the instruments are only slightly soiled (no visible contamination).

The concentration rates and contact times indicated by the manufacturers of the cleaning agents and disinfectants must be adhered to. Only use freshly prepared solutions, sterile or low-germ (< 10 CFU/ml) and low-endotoxin water (< 0.25 EU/ml, e.g. purified water (PW)), and filtered air for drying.

Process:

1. Cleaning
 - a. Sort the pre-cleaned instruments into your endo module and place it into the LavEndo® box. Cleaning of loose instruments is not permitted.
 - b. Place the instruments or the LavEndo® box horizontally into the cleaning bath for the indicated contact time, the instruments must be sufficiently covered (if necessary with ultrasonic support or careful brushing with a soft brush).
 - c. Then remove the instruments from the cleaning bath and rinse them thoroughly with water (minimum of 3 x for 1 min.).
2. Disinfection
 - a. Place the cleaned and inspected instruments in the LavEndo® box into the disinfection bath for the indicated contact time;

the instruments must be sufficiently covered.

- b. Then remove the instruments from the disinfection bath and rinse them thoroughly with water for at least 5 min.
- c. Inspect, dry and pack the instruments as quickly as possible after removal (see chapter Inspection, Service and Packing).

Instruments and products which cannot be cleaned in the LavEndo® box must be disassembled – if possible. Please also note that the instruments/products may not touch.

Inspection

Check all instruments after cleaning or cleaning / disinfection. Defective instruments should be immediately discarded.

These defects include:

- plastic deformation
- bent instrument
- untwisted threads
- damaged cutting surfaces
- dull cutting blades
- missing size mark
- corrosion

Information on the frequency of use is shown in the chapter “Re-use”. Instruments which are still contaminated must be cleaned and disinfected again.

Instrument Maintenance

Re-assemble the disassembled instruments. Instrument oils may not be used.

Packing

Please pack the instruments into the endo-sterilisation trays and then in disposable sterilisation pouches (disposable packaging) meeting the following requirements:

- compliance with DIN EN 11607/ANSI AAMI ISO 11607
- suitable for steam sterilisation (temperature resistant up to min. 138 °C (280 °F), sufficient vapour permeability)

Check the manufacturer’s date of expiry on the sterilisation packaging to ensure it can still be used.

Re-Processing in Line with DIN EN ISO 17664

Sterilisation

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

Steam sterilisation

- Fractional vacuum/pre-vacuum method (at least 3 vacuum cycles) or gravity displacement method¹ (product must be sufficiently dry)
- Steam steriliser according to DIN EN 13060 or DIN EN 285
- Validated according to DIN EN ISO 17665. [Valid installation and operation qualification (IQ and QR) and product-specific performance qualification (PQ)]
- Maximum sterilisation temperature 138 °C (280 °F); plus tolerance according to DIN EN ISO 17665
- Sterilisation time (exposure time at sterilisation temperature) at least 20 min. at 121 °C (250 °F) or 5 min.² at 132 °C / 134 °C (270/273 °F)

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

² Or 18 min. (prion inactivation)

The rapid sterilisation method or the sterilisation method of unpacked instruments is not permitted.

In addition, do not use any hot air sterilisation, no radiation sterilisation, no formaldehyde or ethylene oxide sterilisation and no plasma sterilisation.

Storage

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

Important Information on Material Resistance

When selecting cleaning and disinfecting agents:

- please ensure that the desinfectant does not contain phenol, strong acids (pH <6) or strong bases (pH >8) and
- that no anticorrosion solutions are used on steel instruments, i. e. solutions must not contain aldehyde or di- and triethanolamine.
- NiTi instruments will be damaged if exposed to a sodium hypochlorite (NaOCl) solution (> than 5%) for more than 5 minutes.
- Hydrogen peroxide solutions (H2O2) will damage NiTi and hand instruments as well as plastic stands
- all chemicals used must be suitable for the respective

instrument

Never clean instruments and sterilisation trays with metal brushes or wire wool.

All instruments and sterilisation trays may not be subjected to temperatures higher than 138 °C (280 °F)

Boxes:

Please ensure that the instrument box does not touch the inner walls or the bottom of the autoclave. Temperatures there can exceed the pre-set temperature, which can lead to material deformation. Only use the designated storage and cleaning inserts to store the instrument boxes. Do not use the boxes as containers for inserting instruments in cleaning/desinfecting solutions. This could make the plastic brittle.

Re-use

Instruments can be reused several times – with proper care and if they are not damaged and contaminated; see the following table. Each re-use or application of non-validated methods is the sole responsibility of the user.

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.

Re-Processing in Line with DIN EN ISO 17664

Instruments/product	Material	Special instructions on cleaning/sterilisation	Re-use	Possible damage in case instructions for use are not followed
K-reamer, Flexicut files, K-files, Hedstrom files, C-PILLOT® files, MC-instruments, probes, root fillers, spreaders, pluggers, Gates, Peeso, B-reamers	Stainless steel and temperature-resistant plastic		Clean and undamaged instruments can be re-used 8 to 10 times Re-use of undamaged pluggers is not limited.	Cracks on plastic handle, corrosion on working part and/or shaft
FlexMaster® and Mtwo® instruments		Please consult respective Directions for Use (see also www.vdw-dental.com).		
NiTi K-files, NiTi finger spreaders NiTi Machtou pluggers	NiTi alloy and temperature-resistant plastic	Do not submerge longer than 5 min. in 5% NaOCl solution	Cleaned and undamaged instruments can be re-used up to 8 times, depending on the curvature of the canals prepared. Re-use of NiTi finger spreaders and NiTi Machtou pluggers: unlimited (check for wear and tear)	Cracks on plastic handle, corrosion on working part and/or shaft
Minifix	Temperature-resistant plastic	For sterilisation shrink-wrap in a disposable sterilisation pouches.	Approx. 50 sterilisation cycles	Deformation of plastic material in case of exceeded sterilisation temperature and/or time
Endo boxes, endo modules, LavEndo® washing box, Interim stand	Temperature-resistant plastic	When using boxes with perforated base, insert autoclave paper first. For sterilisation the tray must be shrink-wrapped in a disposable sterilisation pouch.	Approx. 50 sterilisation cycles	Cracks or deformation of plastic material in case of exceeding max. sterilisation temperature and/or time

Single-Use

RECIPROC® instruments		Please consult respective Directions for Use (see also www.RECIPROC.com)		
Barbed broaches	Stainless steel and temperature-resistant plastic	Non-sterile instruments only: One single sterilisation prior to use	Only for single-use	Proper removal of pulpal tissue remnants from the barbs cannot be guaranteed
Foam disks for Interim stand	Foam	Can be autoclaved prior to single-use	Only for single-use	Foam material can dissolve if used several times
Silicone stoppers	Silicone	Silicone stoppers should be removed before cleaning / disinfection and cleaned/ disinfected separately	We recommend using stoppers only once	Proper cleaning of hole cannot be guaranteed
Silver points	Silver	Please consult respective Directions for Use (available: www.vdw-dental.com)	Only for single-use	Risk of contamination, deformation, attached sealer remnants etc.
Paper points	Paper		Only for single-use	Risk of contamination, deformation, loss of absorbance
Gutta-percha points	Gutta-percha, zinc oxide and barium sulphate	Cold disinfection, e.g. in med. alcohol	Only for single-use	Risk of contamination, deformation, adhesion of sealer etc.

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

Hand instruments

Indication: root canal treatment Contra-indications: none known (short-time application)

When used in an endo-contra-angle, see  Instruments for contra-angle

Manufacturer: VDW GmbH










Instrument/Product	Application
K-reamers, REF 053, 353, 705 K-files, REF 063, 363, 706 Flexicut® files, REF 064, 364, 704 C-PILOT® files, REF 368	Pushing/rotating motion (reaming motion) max. 90° clockwise Filing motion, max. 45° clockwise. Standard processing methods, e.g. step back, step down, standardised method, balanced force.
NiTi K-files, REF 263, 362	NiTi K-files must always be used manually! Pushing and pulling motion without rotation. Rotating motion would cause the sharp blades to block.
Hedstroem files, REF 073, 373, 707	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, REF 069, 079	Pushing and pulling motion without rotation.
Barbed broaches, REF 033, 333 (Exstirpation needles)	Push into the canal and pull out following a rotating motion of approx. 180°
Finger spreaders, REF 095, 395 NiTi Finger spreaders, REF 295, 392	Lateral condensation of gutta-percha points. The spreader is placed between the points and pushed carefully in apical direction.
Finger pluggers, REF 099, 399 Machtou pluggers, REF 1063	Vertical condensation of gutta-percha points. Carefully condense the gutta-percha points with the blunt instrument tip.

Instruments for contra-angle and hand instruments used in contra-angles

Manufacturer: VDW GmbH

Indication: root canal treatment Contra-indications: none known (short-time application)

Pull on the instrument to check if it is firmly locked in the contra-angle. Note the instructions in the manufacturer'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.reciproc.com)	
K-reamers C.A., REF 058	Green contra-angle, max. 800 rpm.	
Hedstroem files C.A., REF 078	In yellow contra-angle only with 1/4 rotation, 450 – 800 rpm	
Beutelrock reamers B2 REF 944	Green contra-angle, to be used only for the straight part of the canal, due to high perforation risk.	
Beutelrock enlargers B1 REF 947	Green contra-angle, 450-800 rpm. Use only to clear the canal access and to enlarge the coronal part.	
Peeso enlargers REF 183	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 enlargers REF 180, 380, 708	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" REF 093, 393, 709	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, REF 179	Indication: adjustment of the working length of endo instruments, gutta-percha and paper points. Contra-indications: none known. Instruments: Place the stopper in the right-hand groove 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.

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