Instructions for the use and preparation for re-use

Preparation for re-use according to DIN EN ISO 17664

General principles

All instruments must be cleaned, disinfected and sterilized priorto each use. This also applies to the first use of instruments supplied non-sterile. Thorough cleaning and disinfection are essential prerequisites for effective sterilisation. The specific instructions for cleaning/sterilisation must be applied according to the instruction manuals of the instruments. 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, sterilizer) are regularly serviced and inspected and that the validated parameters are maintained with each cycle.
In addition, always observe the validated legal regulations and regulations on hygiene relating to your practice or the hospital. This applies in particular to the guidelines regarding effective prion inactivation.
For your own safety, always wear gloves when handling contaminated instruments.

Cleaning and disinfection

Basic principles

If possible, a mechanical method (disinfector) should be used to clean and disinfect the instruments. A manual method – including the ultrasonic bath – should, due to their reduced effectiveness and reproducibility, only be used if a mechanical method is not available. The pre-treatment process should be performed in every case.

Pre-treatment

Pulp and dentin residues must be removed immediately from the instrument (within maximum 2 hrs). Do not let them dry! 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 or clean in a disinfecting solution to remove contamination. The disinfectant should be aldehyde-free (aldehyde fixes blood stains), tested for effectiveness (e.g. DGHM or FDA certification or CE mark), suitable for instrument disinfection and compatible with the instruments (see chapter “Material Resistance”). Only use clean, soft brushes to manually remove contamination or a clean, soft cloth which you only use 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/RDG)

When purchasing the disinfector, always ensure:

- that its effectiveness has been tested (e.g. 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 ºC or A-value >3000) (chemical disinfection risks leaving residues on the instruments)
- that the programme for instrument disinfection is suitable and provides sufficient rinsing cycles
- that only sterile or low-germ and endotoxin-free water (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. 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 “Material Resistance”).

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

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Process:

1. Sort the pre-cleaned instruments into your endo module. Cleaning of loose instruments is not permitted.
2. Place the box into the disinfector
3. Start the program
4. When the program has run, remove the box from the disinfector
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, Service and Packing).

Instruments and products which cannot be cleaned in the 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 (no foam is formed)
- that a disinfectant with tested effectiveness is used (e.g. 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 "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 and low-endotoxin water (e.g. purified water (PW)), and filtered air for drying.

The washer-disinfector is not recommended for devices made of aluminium, tungsten carbide or carbon steel.

Process:

1. Cleaning

a. Sort the pre-cleaned instruments into your endo module. Cleaning of loose instruments is not permitted.
b. Place the instruments or the box horizontally into the cleaning bath for the prescribed 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 for at least 1 min. thoroughly with water.

2. Disinfection

a. Place the cleaned and inspected instruments in the box into the disinfection bath for the prescribed 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 1 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 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.

Service

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 packages (disposable packaging) meeting the following requirements:

- compliance with DIN EN 868/ANSI AAMI ISO 11607
- suitable for steam sterilisation (temperature resistant up to min. 141 ºC, sufficient vapour permeability)

Sterilisation

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

Steam sterilisation

- Fractional vacuum method or gravitational method[1] (product must be sufficiently dry)
- Steam sterilizer according to DIN EN 13060 or DIN EN 285
- Validated according to DIN EN 554 / ANSI AAMI ISO 11134
- (Valid commissioning and product-specific performance assessment)
- Maximum sterilisation temperature 138 ºC (280 ºF); plus tolerance according to DIN EN 554/ ANSI AAMI ISO 11134
- Sterilisation time (Exposure time at sterilisation temperature) at least 20 min. (at 121 ºC (250 ºF)) or 5 min2 at 132 ºC / 134 ºC (270 ºF)

[1] The less effective gravitational method should only be used when 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.

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

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Storage

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

Material resistance

When selecting the cleaning and disinfecting agents, please ensure that they do not contain phenol, strong acids or strong alkaline disinfectants or anticorrosion solutions. Do not submerge in the NaOCl solution for longer than 3 hours. All instruments and sterilisation trays may not be subjected to temperatures higher than 141 ºC (286 ºF)!

Re-use

The 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.

Instruments/product	Material	Special instructions on cleaning/sterilisation	Re-use	Possible damage due to failure to follow instructions for use
K-reamer, K-files, Hedstroem files, root canal paste fillers, spreaders, pluggers,, Gates, Peeso	Stainless steel and temperature resistant plastic material		Clean and non-damaged instruments can be re-used 8 to 10 times Re-use of non-damaged pluggers is not limited.	Cracks on plastic handle, corrosion on working part/ and/or shaft
arbed broaches	Stainless steel and temperature resistant plastic material		For single use only	
NiTi Instruments	NiTi alloy and temperature resistant plastic material		Clean and non-damaged instruments can be re-used 8 to 10 times, depending on canal curvature. Follow detailed user manual.	Corrosion on working part and/or shaft
NiTi K-files, Niti finger spreaders	NiTi alloy and temperature resistant plastic	Do not submerge longer than 5 min. in NaOCl solution	Same as NiTi Instruments NiTi finger spreader: unlimited (check for wear)	Cracks on plastic handle, corrosion on working part and/or shaft
Mouth mirror holders	Stainless steel and temperature resistant plastic material	Cleaning only in a disassembled state		Stiffness of the threading. Disinfectant residue can look like rust
Endo boxes, Interim stand	Temperature resistant plastic material	When using boxes with perforated base. Insert autoclave paper first. For sterilisation the tray must be shrink-wrapped into a disposable sterilisation package.		
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	
Guttapercha points	Natural guttapercha Zinc oxide and barium sulphate	Cold disinfection e.g. in med. alcohol	Single use only	Deformation
Stainless steel burs, tungsten carbide burs	Stainless steel, tungsten carbide		Safest to use only once, if re-used check carefully for damage. Clean and non-damaged instruments can be re-used.	Cracks, deformations (bent, unwound), corrosion, loss of color coding or marking