INSTRUCTIONS FOR CLEANING, DISINFECTION AND STERILIZATION OF DFS INSTRUMENTS

EN

Preparation (cleaning, disinfection and sterilization) of reusable rotary dental instruments

According to DIN EN ISO 17664

General principles

All instruments must be cleaned, disinfected and sterilized before each use; this applies in particular to the first use after delivery since all instruments are shipped non-sterile (cleaning and disinfection after removing the protective transport packaging; sterilization after packaging). Efficient cleaning and disinfection are indispensable prerequisites for effective sterilization.

Please note the following within the scope of your responsibility for the sterile use of your instruments:

- only those procedures sufficiently validated for cleaning / disinfection and sterilization of the specific devices and products are always used,
- the equipment used (WD, sterilizer) is regularly serviced and inspected and
- the validated parameters are complied with for each cycle.

Please observe also the legal regulations applying in your country as well as the hygiene regulations of the medical office or hospital. This applies especially for the different stipulations regarding effective prion inactivation (not applicable for the U.S.).

Cleaning and Disinfection

Basics

A mechanical method (WD (Cleaning and Disinfection Device)) should preferably be used for cleaning and disinfection. A manual procedure – because of the significantly lower effectiveness and reproducibility, even when using an ultrasonic bath – should only be used if a mechanical procedure is not available.

Pretreatment shall be performed in both cases.

Pretreatment

Coarse soiling must be removed from the instruments immediately after their use (within max. 2 hours):

Procedure:

1. Disassemble the instruments as much as possible (refer to the chapter “Special Notes”).
2. Rinse the instruments at least for 1 min under running water (temperature < 35 °C/95 °F).
   If applicable (see chapter “Special Notes”):
   Rinse all lumina of the instruments three times using a disposable syringe (min. volume 5 ml) with a disposable needle attached.
3. Place the disassembled instruments at least for the provided action time in the pre-cleaning bath[1] so that the instruments are sufficiently covered. Make sure the instruments do not touch each other. Support pre-cleaning by completely brushing off all inside and outside surfaces (at the beginning of the action time, auxiliary means, see chapter “Special Notes”) and ultrasound use (for the minimum action time, but not less than 5 min).
   If applicable (see chapter “Special Notes”):
   Rinse all lumina of the instruments at least three times using a disposable syringe (min. volume 5 ml) with a disposable needle attached.
4. Activate the ultrasound again for the specified action time (but not less than 5 min).
5. Now remove the instruments from the pre-cleaning bath and follow by rinsing them thoroughly at least three times (at least 1 min) with water.
   If applicable (see chapter “Special Notes”):
   Rinse all lumina of the instruments at least three times using a disposable syringe (min. volume 5 ml) with a disposable needle attached.
6. Check the instruments. In case of visible residue repeat steps 2 to 4 and check again. Discard the instrument if residue is still visible.

Make sure when selecting the cleaning agent[1] that

- it is principally suitable for cleaning instruments from metals and plastics,
- the cleaning agent – if applicable – is suitable for ultrasonic cleaning (no foam development),
- the cleaning agent is compatible with the instruments (see chapter “Material resistance”).

The concentrations, temperatures and action times as well as stipulations for follow-up rinsing specified by the manufacturer of the cleaning agent or cleaning and disinfection agents must be absolutely complied with. Use only solutions that have been freshly prepared as well as water that is sterile or has a low-microbe count (max. 10 microbes/ml) as well as low-endotoxin content (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water); for drying, use only a soft, clean and lint-free cloth and/or filtered air.

[1] If – e.g. for occupational protection reasons – you are using a cleaning and disinfection agent, please remember that it should be free from aldehydes (otherwise fixing of blood soiling), should have certified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), is suitable for disinfection of the instruments and compatible with the instrument (see chapter “Material resistance”). Please note that the disinfectant used for pretreatment is only for personal protection and cannot replace the disinfection step to be carried out later, after cleaning has taken place.

Mechanical cleaning / disinfection (WD (Cleaning and Disinfection Device)

Make sure when selecting the WD,
- that the WD principally complies with DIN EN ISO 15883 and has a certified effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking),
- that, if possible, a certified program is used for thermal disinfection (A_0 value > 3000 or – with older devices – at least 5 min at 90 °C/194 °F) (with chemical disinfection there is a risk of disinfectant residues on the instrument),
- that the program used is suitable for the instruments and has sufficient rinse cycles,
- that only water that is sterile or has a low-microbe count (max. 10 microbes/ml) as well as low-endotoxin content ((max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water) is used for follow-up rinsing,
- that the air used for drying is filtered (oil-free, low microbe and particle content) and
- that *the* WD is regularly serviced and inspected.

Make sure when selecting the cleaning agent system,
- that it is principally suitable for cleaning instruments from metals and plastics,
- that – if no thermal disinfection is used – a suitable disinfection agent with certified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is used in addition and that this is compatible with the cleaning agent used and
- that the chemicals used are compatible with the instruments (see chapter “Material resistance”).

The concentrations, temperatures and action times as well as stipulations for follow-up rinsing specified by the manufacturer of the cleaning agent or disinfection agent must be absolutely complied with.

Procedure:

1. Disassemble the instruments as much as possible (refer to the chapter “Special Notes”).
2. Place the disassembled instruments in the WD using a small parts basket.
3. Start the program.
4. Remove the instruments from the WD after the program is completed.
5. Check and package the instruments immediately after removal, if possible (see chapter “Control and Maintenance” and “Packaging”, if necessary, after additional follow-up drying at a clean location).

Evidence of the general qualification of the instruments for an effective mechanical cleaning and disinfection was provided by an independent , officially accredited and recognized (§ 15 (5) MPG) test laboratory using the WD G 7836 CD (thermic disinfection, Miele & Cie. GmbH & Co., Gütersloh) and pre-cleaning and cleaning agent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was considered.

Manual cleaning and disinfection

Make sure when selecting the cleaning and disinfection agents to be used,
- that they are principally suitable for cleaning and disinfecting instruments from metals and plastics,
- that the cleaning agent – if applicable – is suitable for ultrasonic cleaning (no foam development),
- that a disinfection agent with certified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is used and that this is compatible with the cleaning agent used and
- that the chemicals used are compatible with the instruments (see chapter “Material resistance”).

Cleaning agent/disinfectant combinations should not be used, if possible. Cleaning agent/disinfectant combinations may be used only in cases of very low contamination (no visible contamination).

The concentrations, temperatures and action times as well as stipulations for follow-up rinsing specified by the manufacturer of the cleaning and disinfection agent must be absolutely complied with. Use only solutions that have been freshly prepared as well as water that is sterile or has a low-microbe count (max. 10 microbes/ml) as well as low-endotoxin content ((max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water); for drying, use only a soft, clean and lint-free cloth and/or filtered air.

Procedure:

Cleaning

1. Disassemble the instruments as much as possible (refer to the chapter “Special Notes”).
2. Place the disassembled instruments at least for the provided action time in the cleaning bath so that the instruments are sufficiently covered. Make sure the instruments do not touch each other. Support cleaning by completely brushing off all inside and outside surfaces with a soft brush
   If applicable (see chapter “Special Notes”):
   Rinse all lumina of the instruments at least five times using a disposable syringe (min. volume 5 ml) with a disposable needle attached.
3. Activate the ultrasound again for the specified action time (but not less than 5 min).
4. Now remove the instruments from the cleaning bath and follow by rinsing them thoroughly at least three times (at least 1 min) with water.
   If applicable (see chapter “Special Notes”):
   Rinse all lumina of the instruments at least five times using a disposable syringe (min. volume 5 ml) with a disposable needle attached.
5. Check the instruments (see chapter “Control and Maintenance”).

Disinfection

6. Place the disassembled, cleaned and checked instruments for the provided action time in the disinfection bath so that the instruments are sufficiently covered. Make sure the instruments do not touch each other.
   If applicable (see chapter “Special Notes”): Rinse all lumina of the instruments at least five times at the beginning and the end of the action time using a disposable syringe (min. volume 5 ml) with a disposable needle attached.
7. Now remove the instruments from the disinfection bath and follow by rinsing them thoroughly at least five times (at least 1 min) with water.
   If applicable (see chapter “Special Notes”): Rinse all lumina of the instruments at least five times using a disposable syringe (min. volume 5 ml) with a disposable needle attached.
8. Dry the instruments by blowing them off/out with filtered compressed air.
9. Package the instruments immediately after removal, if possible (see chapter “Packaging”, if necessary, after additional follow-up drying at a clean location).

Evidence of the general qualification of the instruments for an effective manual cleaning and disinfection was provided by an independent , officially accredited and recognized (§ 15 (5) MPG) test laboratory using pre-cleaning and cleaning agent Cidezyme/Enzol and disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). The procedure described above was considered.

Control and Maintenance

Check all instruments after cleaning or cleaning / disinfection for corrosion, damaged surfaces, chipping, soiling as well as discolorations, and sort out damaged instruments (numbered limitation of reuse, see chapter “Reusability”). Instruments that are still soiled must be cleaned and disinfected again.

Reassemble the disassembled instruments (see chapter “Special Notes”).

Instrument oils or greases must not be used.

Packaging

Please package the instruments in disposal sterilization packaging (single or double-packaging), meeting the following requirements (material / process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for the U.S.: FDA clearance)
- Suitable for steam sterilization (temperature resistance up to min. 138 °C (280 °F) adequate vapor permeability)
- Sufficient protection of the instrument or sterilization packaging against mechanical damages

Sterilization

Only the sterilization processes listed below shall be used for sterilization; other sterilization processes are not permitted.

Steam sterilization

- Fractionated vacuum process[2, 3] (with adequate product drying[4])
- Steam sterilizer according to DIN EN 13060/DIN EN 285 o ANSI AAMI ST79 (for the U.S.: FDA clearance)
- Validated according to DIN EN ISO 17665 (valid IQ/OQ (picking & packing) and product-specific performance assessment (PQ))
- Maximum sterilization temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665)
- Sterilization time (exposure time with sterilization temperature):

Country	Fractionated vacuum process	Gravitation process
U.S.	min. 4 min at 132 °C (270 °F), drying time min. 20 min[4]	not recommended
other countries	min. 5 min[5] at 132 °C (270 °F) / 134 °C (273 °F)	not recommended

[2] min. three vacuum steps
[3] Use of the less effective gravitation process is permitted only if the fractionated vacuum process is not available; it requires much longer sterilization times and must be validated at the sole responsibility of the user in regard to the product, device, process and parameters.
[4] The actual drying time required depends directly on parameters at the sole responsibility of the user (loading configuration and spacing, sterilizer condition, ...) and must therefore be determined by the user. Nonetheless, drying times should not be shorter than 20 min.
[5] or 18 min (prion inactivation, not relevant for the U.S.)

Evidence of the general qualification of the instruments for an effective steam sterilization was provided by an independent , officially accredited and recognized (§ 15 (5) MPG) test laboratory using steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and fractionated vacuum process. Typical conditions in clinics and surgery as well as the procedure described above were considered.

The rapid sterilization process is principally not permitted.

Also, do not use any hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization as well as plasma sterilization.

Storage

After sterilization the instruments must be stored dry and dust-free in the sterilization packaging.

Material resistance

Please ensure when choosing the cleaning and disinfection agent that they do not contain the following ingredients:

- Organic, mineral and oxidizing acids (minimum permissible pH value 6.5)
- Alkaline solutions (maximum permissible pH value 8.5, neutral/enzymatic cleaner recommended)
- Organic solvents (e.g. alcohols, ethers, ketones, benzenes)
- Oxidants (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromide)
- Aromatic/halogenated hydrocarbons

Never clean any instruments with metal brushes or steel wool.

All instruments must not be exposed to temperatures higher than 138 °C (280 °F)!

Reusability

When exercising appropriate care and if the instruments are not damaged or soiled, they can be reused up to the number of times listed in the chapter “Special Notes”; any continued use beyond this or the use of damaged and/or soiled instruments is at the responsibility of the user.

Any liability is excluded in case of disregard.

Additional information

Do not store instruments in plastic bags

Contact to manufacturer:

Email: info@dfs-diamon.de, Phone: +49 (0)9442 9189 0

Special Notes

Genus	Product name	Rinse volume	Brush	Special/additional procedure for				Packaging	Sterilization	Max. permissible number of cycles	Classification recommendations in accordance with KRINKO/RKI/BfArM recommendation (Germany only, if used as intended)
				Pretreatment	Manual cleaning / disinfection	Mechanical cleaning / disinfection	Maintenance/ Assembly				
Diamond-coated instruments	*Diam. FG und WST, Zircut, Softy-longlife, Miniflex, Crown cutter / Trepanator zirconia, Diafutur, Ultra-Light, Crossy, Wonder Ball*	-	Standard	Standard	Standard	Small parts basket	Oiling not permitted	Standard procedure	Standard procedure	30	*Semi-critical B*
	DIADOSS, ENDO, Perio	-	Standard	Standard	Standard	Small parts basket	Oiling not permitted	Standard procedure	Standard procedure	20	*Critical B*
Carbide instruments	*Rosehead burs, finishers, crown separators, Orthodontic carbide bur*	-	Standard	Standard	Standard	Small parts basket	Oiling not permitted	Standard procedure	Standard procedure	20	*Semi-critical B*
	Bone cutters, ENDO, Paros	-	Standard	Standard	Standard	Small parts basket	Oiling not permitted	Standard procedure	Standard procedure	20	*Critical B*
Steel instruments	*Bone cutters*	-	Standard	Standard	Standard	Small parts basket	Oiling not permitted	Standard procedure	Standard procedure	5	*Critical B*
	Tissue punch	-	Standard, interdental brush, conical	Standard, brush in addition on inside with interdental brush, check in addition for tissue residues inside (and repeat pre-cleaning, if necessary)	Standard, brush in addition on inside with interdental brush,	Small parts basket	Oiling not permitted	Standard procedure	Standard procedure	15	*Critical B*
Ceramic instruments	*PreciCut*	-	Standard	Standard	Standard	Small parts basket	Oiling not permitted	Standard procedure	Standard procedure	15	*Critical B*
Solids	Polisher	-	Standard	Standard	Standard	Small parts basket	Oiling not permitted	Standard procedure	Standard procedure	10	*Semi-critical B*
	Prophylaxis polisher	5 ml	Standard, interdental brush, conical	disassemble, then standard, brush cavity in addition with interdental brush, flush back cavity in addition with disposal syringe and attached needle	Standard (disassembled), brush cavity in addition with interdental brush, flush back cavity in addition with disposal syringe and attached needle	Small parts basket (disassembled)	Oiling not permitted	Standard procedure (disassembled)	Standard procedure (disassembled) Assembly before reuse with sterile gloves	10	*Semi-critical B*
Brushes	Uporal polisher	-	Standard	Standard, spread bristles in addition with follow-up rinsing	Standard, spread bristles in addition with follow-up rinsing	Small parts basket	Oiling not permitted	Standard procedure	Standard procedure	10	*Semi-critical B*