General recommendations for the safe use and application of dental rotary instruments (medical devices according to MDD 93/42/EC)

EDGE DIAMONDS need to be sterilized before every use on the patient. This applies as well to single-use instruments (except felts) prior to first use. Single-use instruments have to be discarded after use.

Our instruments have been developed and designed for their specific use. Improper use can lead to damage to tissues, premature wear, destruction of the instruments and may cause danger to users, patients or third parties. Rotary instruments for use in medical applications are to be used only by doctors or other experts who are adequately skilled, trained and experienced in the safe handling of these instruments.

1. Proper use

• Only handpieces, turbines and contra-angles that are in perfect technical and hygienic condition may be used.
• The instrument must be rotating at the appropriate speed before contact is made with the workpiece, tissue, etc.
• Insert the instruments into the chuck as deeply as possible.
• Avoid jamming and do not use the instrument as a lever as this increases the risk of breakage.
• Wear safety goggles wherever required.
• Avoid unprotected contact with the instruments, the use of protective gloves is strongly recommended.
• When using rotary instruments ensure sufficient cooling (except when the manufacturer recommends use without cooling).

Improper use increases the risk of injury and/or damage and leads to inferior results. Therefore, please follow the application and speed recommendations as indicated on the labels.

2. Recommended speeds

• You will achieve the best results when observing the instrument-specific recommended speed (see product description).
• Long and pointed instruments may break when the recommended speed is exceeded due the possible vibration in the tip area.
• In case of instruments where the diameter of the working part exceeds the diameter of the shank strong centrifugal forces may occur if the selected speed is too high. This may result in bending of the shank and/or breakage of the instrument. The recommended maximum speed must not be exceeded.
• The general rule is: the larger the working part, the lower the selected speed should be.

3. Contact pressure

• Excessive contact pressure must be strictly avoided.
• Excessive contact pressure can cause thermal damage to the tooth or the pulp. Moreover, it may lead to undesirably rough surfaces due to broken blades.

4. Cooling

• In order to avoid undesirable heat generation sufficient cooling with air/water mix of min. 50mL/min needs to be provided during preparation.
• When using FG instruments sufficient water cooling needs to be provided continuously.
• Insufficient cooling may cause permanent damage to the tooth, surrounding tissue and/or pulp.

• Coarse and extra-coarse grit diamonds may lead to increased thermal stress. When using these instruments ensure sufficient cooling and work with minimal contact pressure. After using these instruments, subsequent finishing (fine diamonds or carbides) is required.

5. Frequency benchmark for the application of rotary instruments

The following values serve as a reference only; the actual service life may differ depending on the application, usage and material but must not exceed the maximum number of reprocessing cycles.

• Diamond instruments 30x
• Carbide instruments 20x

6. Elimination of worn instruments

Blunt and damaged instruments may encourage the user to apply excessive contact pressure, which in turn generates increased operating temperatures. As this can result in permanent pulp damage, instruments showing wear, damage or which are blunt have to be discarded immediately.

7. Disposal

Used instruments must be discarded with general clinical waste.

8. Additional remarks

Please refer to the product descriptions on the respective catalog pages for more information. Instructions for use are available electronically at www.clinicianschoice-ifu.com.

INSTRUCTIONS FOR CLEANING, DISINFECTION AND STERILIZATION

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

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 pre-requisites 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 (CDD, 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 (CDD (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.

Pre-treatment shall be performed in both cases.

Pre-treatment
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.
2. Rinse the instruments at least for 1 min under running water (temperature < 35°C/95°F). If applicable: 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 and ultrasound use (for the minimum action time, but not less than 5 min). If applicable: 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: Rinse all lumina of the instruments at least three times using a disposable syringe (min. volume 5 ml) with a disposable needle attached.

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 (CDD (Cleaning and Disinfection Device)

Make sure when selecting the CDD,

- that *the* CDD principally has a certified effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking according to DIN EN ISO 15883),
- 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* CDD 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.
2. Place the disassembled instruments in the CDD using a small parts basket.
3. Start the program.
4. Remove the instruments from the CDD after the program is completed.
5. Check and package the instruments immediately after removal, if possible (see chapters “Maintenance” and “Packaging”, if necessary, after additional follow-up drying at a clean location).

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.
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: 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: 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 “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: 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: 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).

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.

Maintenance
Reassemble the disassembled instruments.
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.)

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)!

Additional information

Do not store instruments in plastic bags

Contact to manufacturer:

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