Application Notes and Reprocessing Recommendation (Polisher, EN)

Language variant English · Polisher · Rev. 3

1. APPLICATION NOTES

1.1 INTENDED PURPOSE

The Polisher, Dental are intended for polishing and finishing procedures in dental applications in clinics and hospitals.

1.2 PROPER USE

All rotatec polishers have been designed and engineered for their specific application. Improper use can lead to tissue damage, increased wear or destruction of the polisher, as well as cause risks to the user, the patient or third parties.

- Only turbines, handpieces and contra-angle attachments that are in perfect technical and hygienical conditions should be used, meaning that they should be well maintained and correctly cleaned. Turbines and contra-angle attachments used must ensure precise and concentric rotation.
- Instruments must be inserted as far as possible. Before applying the instruments to any surface, they must be brought to speed.
- If possible, polish in slightly circular movements to avoid indentations.
- Tilting or levering is to be avoided as it leads to an increased risk of breakage.
- Immediately discard any deformed or non-concentric rotary instruments.
- Unmounted polishers must be centred after mounting in order to avoid vibrations during use. Only high quality mandrels must be used. Inferior mandrels can break and cause injury.
- Protective goggles should be worn at all times. In case of improper use or material failure, mandrel, shank or workpiece could break and become dangerous flying objects. Alternatively the user can work behind a protective glass pane.
- Respiratory protection must be worn to avoid inhaling dust. Moreover, a dust extraction system is recommended.

Improper use leads to poor application results and increased risks. rotatec products must only be used by qualified personnel.

1.3 ROTATION SPEED INSTRUCTIONS

- Never exceed the maximum rotation speed. The recommended and maximum rotation speeds do vary between products. Make sure to check the recommended and maximum speeds in our latest catalogues and packaging.
- In case of exceeding the maximum rotation speed, polishers tend to vibrate. Such vibrations can destroy the polisher, deform the shank and/or cause the instrument to break. Consequently, the user, the patient and third parties could be injured.
- Compliance with the recommended speed range leads to best possible work results.

Non-observance of the maximum permitted speed leads to an increased safety risk.

1.4 APPLICATION PRESSURE

- Excessive pressure can destroy the polisher.
- Excessive pressure leads to increased heat development.
- Excessive pressure can lead to increased wear of the polisher.

Excessive pressure is to be avoided as it causes overheating, which could damage the pulp. In extreme cases instruments can break and cause injuries.

1.5 WATER COOLING

- In order to avoid unwanted heat development on the tooth, sufficient water cooling is required (at least 50 ml/min).

Insufficient water cooling can lead to irreversible damage to the tooth and its surrounding tissues.

2. REPROCESSING RECOMMENDATION ACCORDING TO EN ISO 17664

2.1 GENERAL NOTES

- Observe the manufacturer's information on material compatibilities for cleaning, disinfection and sterilisation.
- All instruments are delivered unsterile and must go through the indicated cycle before and after each use.
- Strong acids and strong bases may oxidise the stainless steel shank.
- Avoid temperatures >150 °C.
- Ultrasonic bath must not exceed temperatures of 42 °C because of the possible coagulation of protein.
- Instruments that have not completely dried after cleaning and disinfection must be dried again (e.g. with medical compressed air) to avoid compromising the success of sterilisation.
- Cleaning and/or disinfecting solutions must specifically state „suitable for rubber polishers or synthetics/silicones“. The exposure time and concentration specified by the manufacturer must be followed.

2.2 RESTRICTION OF REPROCESSING

Disposable products delivered unsterile, marked with the symbol ⊘, may only go through the validated sterilisation cycle ONCE before initial use. The medical devices K12 and K15 were also sprayed for an additional 60 seconds with a water spray gun under high pressure (3.8 bar).

2.3 RISK ASSESSMENT AND CLASSIFICATION OF MEDICAL DEVICES BEFORE REPROCESSING

The type and scope of reprocessing is determined by the use of the medical device. Therefore, the operator is responsible for the correct classification of the medical devices and thus for the definition of the type and scope of reprocessing (see KRINKO/BfArM recommendation, point 1.2.1 Risk assessment and classification of medical devices prior to reprocessing). On the basis of this user-dependent classification, the operator can determine which of the reprocessing methods listed in this preparation and reprocessing instruction needs to be applied.

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2.4 PLACE OF USE

No special requirements.

2.5 STORAGE AND TRANSPORT

It is recommended to transport the contaminated instruments in a closed container.

It is recommended that instruments be reprocessed as soon as possible, within 2 hours after use at the most. Intermediate storage of used instruments with contamination such as blood residues can lead to corrosion damage.

2.6 PREPARATION

Wear personal protective equipment (durable gloves, water-repellent coat, face protection mask or goggles and protection mask).

2.7 PRE-TREATMENT

Pre-clean under running water with a brush (plastic) directly after use.

Equipment: Plastic brush (e.g. Interlock, #09084), tap water (20± 2 °C) (at least drinking water quality)

1. Rinse the polishers under running water for 60 seconds and brush them thoroughly with a plastic brush, particularly the difficult to access areas of the head (bristles, silicone bristle tips).

2.8 CLEANING: MANUAL

Note: Coarse surface contamination on the instruments must be removed before manual reprocessing (see pre-treatment).

Equipment: Multi-stage enzymatic cleaner (e.g. Dürr Dental, ID 215), tap water/flowing water (20± 2 °C) (at least drinking water quality), ultrasonic bath (e.g. Sonorex Digital 10P)

1. Prepare the cleaning solution according to the manufacturer's instructions (Dürr Dental ID 215 2% solution was validated) and fill into an ultrasonic bath.
2. Completely immerse the polishers in the solution.
3. Expose the products for 1 minute to the ultrasonic bath.
4. Remove the polishers from the cleaning solution and rinse them each thoroughly (30 seconds) under running water.
5. Check for cleanliness. If contamination is still visible, repeat the above specified steps.

2.9 DISINFECTION: MANUAL (WITH SUBSEQUENT STERILISATION)

Equipment: At least limited virucidal instrument disinfectant (VAH listed – or at least listed in the IHO with testing according to DVV) based on quaternary ammonium compound(s), alkylamine(s)/alkylamine derivative(s), guanidine(s)/guanidine derivative(s) (e.g. Dürr Dental, ID 212), preferably fully deionised water (deionised water, according to KRINKO/BfArM recommendation free of facultative pathogenic microorganisms), ultrasonic bath (e.g. Sonorex Digital 10P), lint-free sterile cloth.

1. Prepare the disinfectant solution according to the manufacturer's instructions (Dürr Dental ID 212, 2% solution was validated) and place into an ultrasonic bath.
2. Completely immerse the polishers in the disinfectant solution.
3. Expose the products for 2 minutes to the ultrasonic bath.
4. Further exposure time to the disinfectant solution for 5 minutes according to the disinfectant manufacturer's instructions.
5. Remove the polishers from the disinfectant solution and allow to drip off.
6. Rinse the products with deionised water for 30 seconds.
7. Wipe with a single use sterile lint-free cloth or, if necessary, dry with medical compressed air.

2.10 CLEANING AND DISINFECTION: AUTOMATIC

Note: Coarse surface contamination on the instruments must be removed prior to automatic reprocessing (see pre-treatment).

Equipment: Cleaning and disinfection unit according to DIN EN ISO 15883-1+2 with thermal programme (temperature 90 °C to 95 °C), detergent: mildly alkaline detergent (e.g. Dr. Weigert neodisher MediClean Dental)

1. Place the instruments in a suitable small parts tray or on the load carrier such that all surfaces of the instruments are cleaned and disinfected.
2. Close WD and start programme, see table below for programme sequence.

Prog.-Step	Water	Dosage	Time	Temperature
Pre-rinse	CW		5 min	
Dosage of detergent		According to manufacturer's instructions		According to manufacturer's instructions
Clean	Fully deionised water		10 min	55 °C
Rinse	Fully deionised water		2 min	
Disinfect	Fully deionised water		3 min	A_0-value >3000[1] (e.g. 90 °C, 5 min)
Drying			15 min	Up to 120 °C

[1]Authorities may issue other operational regulations (disinfection performance parameters) in their area of competence.

3. Remove the instruments at the end of the programme.
4. Check that the load is dry and, if necessary, dry with medical compressed air.
5. Visual inspection for cleanliness is performed after removal from the WD. If contamination is still visible, reclean medical devices again manually. Subsequently, the recleaned medical devices must again be reprocessed automatically.

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2.11 MAINTENANCE, INSPECTION AND CHECK

Equipment: Illuminated magnifying glass (3–6 dioptres)

All instruments must be inspected visually for cleanliness, integrity and functionality, if necessary by using an illuminated magnifying glass (3–6 dioptres).

All instruments are to be checked for damage and wear. Damaged medical devices may no longer be used and must be sorted out.

2.12 PACKAGING

Equipment: Film-paper packaging (e.g. steriCLIN, art. no. 3FKFB210112 and 3FKFB210140), sealing device (e.g. HAWO, type 880 DC-V)

A suitable method (sterile barrier system) is to be used to package the instruments. Packaging according to DIN EN ISO 11607.

A sterile barrier system (e.g. film-paper packaging) according to DIN EN ISO 11607 is to be used, which is intended for steam sterilisation by the manufacturer. The instruments are double packed. The packaging must be large enough to avoid stressing the sealing seam.

Note: After the heat sealing process, the sealing seam must be checked visually for any defects. In case of defects, the packaging must be opened and the instrument repacked and sealed.

2.13 STERILISATION

Device: Steriliser according to DIN EN 285 or small steam steriliser according to DIN EN 13060, type B process

Process: Steam sterilisation with fractionated pre-vacuum, 134 °C, holding time min. 3 min (in Germany according to KRINKO/BfArM recommendation 134 °C min. 5 min) or 132 °C min. 3 min (parameter of validation). Longer holding times are possible.

1. Place the packaged products in the sterilisation chamber.
2. Start the programme.
3. Remove the products at the end of the programme and allow to cool down.
4. Then check the packaging for possible damage. Faulted packaging must be regarded as being non-sterile. The instruments must be repacked and sterilised.

2.14 STORAGE

Duration of storage according to own specifications.

It is recommended to store instruments packed and protected from recontamination in proven suitable sterile packaging, cassettes or retainers.

2.15 ADDITIONAL INFORMATION

Disposal note: All polishers can be disposed of in the practice waste after a final sterilisation cycle. A maximum of 10 reprocessing cycles is permitted.

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3. GLOSSARY OF SYMBOLS

Symbol	Meaning
	CE Compliance
	Indicates the authorized representative in the European Community / European Union
	Medical Device
	Manufacturer
	Made-in symbol / country of manufacture
	Expiry date
	Catalogue number / Part Number (P/N)
	Batch code / number
	Unique Device Identifier
	Maximum speed (RPM)
	Packaging unit

4. CONTACT INFORMATION

Symbol	Address
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