Jiffy™ one

Jiffy™ One Single-Use Polishers

Instructions For Use

ULTRADENT PRODUCTS, INC.

Preparation and Reprocessing Instructions in Accordance with DIN/EN ISO 17664

METHOD	SYMBOL	REV STATUS	RELEASE DATE
H		10	2022-06-23

WARNINGS

- Observe the manufacturer's information on material compatibilities for cleaning, disinfection, and sterilization.
- All instruments are delivered unsterile and must go through the indicated cycle before and after each use.
- Strong acids and strong bases may oxidize 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 sterilization.
- Instructions of 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.

RESTRICTION OF REPROCESSING

Disposable products delivered unsterile, marked with the symbol (②), may only go through the validated sterilization cycle ONCE before initial use.

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.

PLACE OF USE:	No special requirements.
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.
PREPARATION:	Wear personal protective equipment (durable gloves, water-repellent coat, face protection mask or goggles, and protection mask).
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).

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.

DISINFECTION: MANUAL

Equipment: At least limited virucidal instrument disinfectant (VAH listed—or at least listed in the IHO with testing according to DW) e.g., based on quaternary ammonium compound(s), alkylamine(s)/alkylamine derivative(s), guanidine(s)/guanidine derivative(s) (e.g., Dürr Dental, ID 212), preferably fully deionized water (deionized water, according to KRINKO/BfArM recommendation free of facultatively 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 deionized water for 30 seconds.
7. Wipe with a single use sterile lint-free cloth or, if necessary, dry with medical compressed air.

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 program (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 program, see table below for program 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 deionized water		10 min	55 °C
Rinse	Fully deionized water		2 min	
Disinfect	Fully deionized water		3 min	Ao-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 program.
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, re-clean medical devices again manually. Subsequently, the re-cleaned medical devices must again be reprocessed automatically.

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.
PACKAGING:	**Equipment**: Film-paper packaging (e.g., steriCLIN, art. no 3FKB210112 and 3FKB210140), sealing device (e.g., HAWO, type 880 DC-V). A suitable method (sterile barrier system) is to be used to package the instruments. Package 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 sterilization 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.
STERILIZATION:	**Device**: Sterilizer according to DIN EN 285 or small steam sterilizer according to DIN EN 13060, type B process. **Process**: Steam sterilization with fractionated pre-vacuum, 134 °C, holding time minimum 3 minutes (in Germany according to KRINKO/BfArM recommendation 134 °C minimum 5 minutes) or 132 °C minimum 3 minutes (parameter of validation). Longer holding times are possible. 1. Place the packaged products in the sterilization chamber. 2. Start the program. 3. Remove the products at the end of the program and allow to cool down. 4. Then check the packaging for possible damage and screening effects. Faulted packaging must be regarded as being non-sterile. The instruments must be repacked and sterilized.
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.
ADDITIONAL INFORMATION:	**Disposal note:** All polishers can be disposed of in the practice waste after a final sterilization cycle. A maximum of 2 reprocessing cycles including final sterilization is permitted.
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Application and Safety Precautions

RECOMMENDATIONS FOR USE OF JIFFY™ ONE SINGLE USE POLISHERS

All Jiffy™ One 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 risk to the user, the patient, or third parties.

PROPER USE:	• Only turbines, handpieces, and contra-angle attachments that are in perfect technical and hygienic 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 slight 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 centered 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. Jiffy™ One products must only be used by qualified personnel.**
ROTATION SPEED: INSTRUCTIONS:	• Never exceed the maximum rotation speed. The recommended and maximum rotation speeds vary between products. Make sure to check the recommended and maximum speeds in our latest catalogs 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.**
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.**
WATER COOLING:	• In order to avoid unwanted heat development on the tooth, sufficient water cooling is required (at least 50 ml/minute). **Insufficient water cooling can lead to irreversible damage to the tooth and its surrounding tissues.**
SYMBOLS:	All used symbols and pictograms according to EN ISO 15223.