

# Instructions for Use – Polishers

Recommendations for use of Polishers-

All Eve polishers have been designed and engineers 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.

## Proper Use-

- 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 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.

## EVE products must only be used by qualified personnel.

## **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.

## **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 / min). Insufficient water cooling can lead to irreversible damage to the tooth and its surrounding tissues.

SYMBOLS- All used symbols and pictograms according EN ISO 15223.

# Preparation and Reprocessing Instructions in accordance with DIN/EN ISO 17664

#### **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**

Repetitive reprocessing can slightly change both the look and feel of the product, but does not interfere with the instrument's function.

## 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 (with subsequent sterilization)**

Equipment: At least limited virucidal instrument disinfectant (VAH listed - or at least listed in the IHO with testing according to DVV) e.g. based on qua-ternary 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 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 ultra-sonic 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.

## **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 > 30001(e.g. 90 °C, 5 min)
Drying			15 min	Up to 120 °C

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, reclean medical devices again manually. Subsequently, the recleaned 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. 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 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 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 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.

## INSTRUCTIONS FOR USE- POLISHING PASTE COMPOSITE

DESCRIPTION- Polishing paste is a 1-step diamond polishing paste with diamond particles for high-gloss polishing of dental composite materials.

COMPOSITIONS- The diamond polishing paste contains diamond particles with a grain size of 4 - 8  $\mu$ m in a carrier matrix made of soft silicone, SLS water and flavors.

INDICATIONS- High-gloss polishing of dental composite materials.

CONTRAINDICATIONS- In case of known allergies to the ingredients of the paste, refrain from use.

NOTES ON APPLICATION- High-gloss polishing is performed with the diamond polishing paste and a nylon brush using minute amounts of water (no spray or flow). The diamond polishing paste is first applied to the cavity of the nylon brush and distributed over the surface to be polished with the nylon brush prior to processing. Any polish residues can be removed with water spray and suctioned off.

## PROPER APPLICATION

- Attention should be paid to using only perfect and hygienically maintained and cleaned turbines, as well as hand pieces or angled pieces.
- Accurate running concentricity of angle piece and turbine is necessary.
- The instruments must be connected correctly.
- Polish with slightly rotating motion to avoid grooving. Avoid tilting or levering to reduce the risk of instrument fracture.
- Brushes which are bent or run untrue may not be used any longer.
- Safety goggles and breathing protection are to be worn as a matter of principle. Ensure efficient aspiration during use.

## Warning

Incorrect use leads to poor polishing results and increased risks.

The product may only be used by qualified persons.

#### PRESSING FORCES

High pressing forces do not lead to better polishing results but increase heat generation. A mean pressing force of approx. 2 N is adequate.

#### Warnings

Excessive pressing forces are to be avoided to exclude overheating during intraoral use which could ultimately lead to damaging the pulp. In extreme cases this could lead to fracture of the instruments and could cause injuries.

#### WATER COOLING

Heat damage to the filling or the pulp is possible. Use interim cooling with spray for applications over 30 seconds. Once polishing has been completed, rinse the residues adequately with water

<u>Warning</u> In case of insufficient water cooling, this can lead to irreversible damage to the tooth and the surrounding tissue

## STORAGE, CLEANING, DISINFECTION AND STERILISATION

- The paste should be stored in its original packaging at room temperature, protected against dust, moisture, pressure and (re)contamination.
- Care should be paid to applying the polishing paste to a sterile surface from the syringe to exclude contamination of the remaining paste in the syringe.
- Store at 2 28°C. Close polishing paste immediately after use.

# Keep out of reach of children! Only for dental use!

# INSTRUCTIONS FOR USE-POLISHING PASTE CERAMIC

## **DESCRIPTION-**

Polishing paste is a 1-step diamond polishing paste with diamond particles for high-gloss polishing of dental ceramic materials.

## **COMPOSITIONS-**

Strauss Diamond Instruments Inc. | 9 Florida Park Drive N., Palm Coast, FL 32137 | Tel: 386-597-7523 Email: Info@Straussdiamond.com | www.Straussdiamond.com The diamond polishing paste contains diamond particles with a grain size of 10 - 12  $\mu$ m in a carrier matrix made of soft silicone, SLS water and flavors.

INDICATIONS- High-gloss polishing of dental ceramic restorations.

#### **CONTRAINDICATIONS-**

In case of known allergies to the ingredients of the paste, refrain from use.

## NOTES ON APPLICATION-

High-gloss polishing is performed with the diamond polishing paste and a nylon brush using minute amounts of water (no spray or flow). The diamond polishing paste is first applied to the cavity of the nylon brush and distributed over the surface to be polished with the nylon brush prior to processing. Any polish residues can be removed with water spray and suctioned off.

## PROPER APPLICATION

- Attention should be paid to using only perfect and hygienically maintained and cleaned turbines, as well as hand pieces or angled pieces.
- Accurate running concentricity of angle piece and turbine is necessary.
- The instruments must be connected correctly.
- Polish with slightly rotating motion to avoid grooving.
- Avoid tilting or levering to reduce the risk of instrument fracture.
- Brushes which are bent or run untrue may not be used any longer.
- Safety goggles and breathing protection are to be worn as a matter of principle.

Ensure efficient aspiration during use.

<u>Warning</u> Incorrect use leads to poor polishing results and increased risks. The product may only be used by qualified persons.

#### PRESSING FORCES-

High pressing forces do not lead to better polishing results but increase heat generation. A mean pressing force of approx.

2 N is adequate.

<u>Warnings</u> Excessive pressing forces are to be avoided to exclude overheating during intraoral use which could ultimately lead to damaging the pulp. In extreme cases this could lead to fracture of the instruments and could cause injuries.

#### WATER COOLING-

Heat damage to the filling or the pulp is possible. Use interim cooling with spray for applications over 30 seconds. Once polishing has been completed, rinse the residues adequately with water

<u>Warning</u> In case of insufficient water cooling, this can lead to irreversible damage to the tooth and the surrounding tissue.

## STORAGE, CLEANING, DISINFECTION AND STERALIZATION

- The paste should be stored in its original packaging at room temperature, protected against dust, moisture, pressure and (re)contamination.
- Care should be paid to applying the polishing paste to a sterile surface from the syringe to exclude contamination of the remaining paste in the syringe. Store at 2 28°C.
- Close polishing paste immediately after use.

Keep out of reach of children! Only for dental use!