

## Instructions for Use - Hasharon Dental – Dental Polishers

### DESCRIPTION

These instructions are valid for Hasharon Dental - Dental Polishers.

**Hasharon Dental's** Dental polishers consist of synthetic/silicone rubber, pigments and abrasive, the shanks are made of stainless steel.

Provided Non-sterile and can be reused.



Please read the following cleaning and sterilization instructions carefully:

### APPLICATIONS:

Hasharon Dental's dental polishers intended for use is for final polishing of composite, Zirconia, Lithium Di-Silicate or so restorations, the dentist will apply composite material for a tooth restoration and then smooth the surface.

### PRECAUTION:

**Contraindications:** If a patient is known to be allergic to any of the above components, the polishers should not be used.

All 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.

### PROPER USE:

- a) 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 .
- b) Instruments must be inserted as far as possible. Before applying the instruments to any surface, they must be brought to speed. check the safe connection of the polisher before using it and perform a test run .
- c) If possible, polish in slightly circular movements to avoid indentations .
- d) Tilting or levering is to be avoided as it leads to an increased risk of breakage .
- e) Immediately discard any deformed or non-concentric rotary instruments .
- f) Protective goggles should be worn at all times .
- g) The dental polishers are intended for dental applications in dental clinics and hospitals by licensed dentist. Rx only
- h) The device is not intended for use for children under six years old.
- i) Always **wear Gloves** when handling contaminated instruments.
- j) **Eye protection** must be worn to protect against ejected particles .
- k) **Surgical mask** must be worn to avoid inhalation of aerosol or dust generated .
- l) **Before each use**, inspect the polishers for damaged blades or excessive wear. **Discard worn polishers.**

### ROTATION SPEED INSTRUCTIONS:

- a) **Do not exceed the maximum speed** - <10,000 RPM. Before applying the instrument on the surface to be treated, bring it to the rotation speed needed.
- b) **Avoid using the polisher at too high an angle in order to avoid leverage and breakage.**

- c) **Move the polisher continuously** when in use to avoid localized heating and/or damage to the polisher.

#### **WATER COOLING**

- a) In order to avoid the overheating of a tooth, sufficient water cooling must be ensured (50 ml/min).

#### **PRESSURE ON THE POLISHER:**

- a) **Do not activate excessive pressure** on the polisher.
- b) Excessive pressure results in more heat being produced.
- c) Excessive pressure can cause early wear of the polisher.

#### **REPROCESSING INSTRUCTIONS FOR MDT POLISHERS**

##### **WARNING NOTICES**

- 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.
- Used Polishers should be considered as being contaminated and appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient.
- Used Polishers are considered as bio-hazard and need to discard as bio-hazard waste unless reprocessing instruction has been done.

##### **CLEANING PREPARATION**

- If manual cleaning is implemented, the polishers should be cleaned in a sink reserved for the purpose .
- Pre-clean under running water with a brush (plastic) directly after use.
- 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.

##### **MANUAL CLEANING :**

- Coarse surface contamination on the instruments must be removed before manual reprocessing
- Clean manually - Under running water with a brush (plastic bristles)

**AUTOMATED - ULTRASONIC :**

- clean with a suitable cleaning agent and disinfectant using multi-stage enzymatic cleaner .
- Prepare the cleaning solution according to the manufacturer's instructions (Dürr Dental ID 215 2% solution was validated) and fill into an ultrasonic bath.
- Completely immerse the polishers in the solution .
- Expose the products for 1 minute to the ultrasonic bath .
- Remove the polishers from the cleaning solution and rinse them each thoroughly (30 seconds) under running water .
- Check for cleanliness. If contamination is still visible, repeat the above specified steps.

**DISINFECTION****MANUAL (WITH SUBSEQUENT STERILIZATION)**

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

**MAINTENANCE**

Visual check of all instruments with optical magnification (5-10 folds).

**INSPECTION:**

No residues - continue to sterilization.

Visible residues - repeat cleaning. Reject and dispose of instruments in the event of discernible defects.

**STERILIZATION****STEAM STERILIZATION:**

- Process: Steam sterilization with fractionated pre-vacuum, 134 °C, holding time min. 3 min or 132 °C min. 3 min (parameter of validation). Longer holding times are possible. Threshold values of contents for feed-water and steam condensates
- Place the packaged products in the sterilization chamber.
- Start the program
- Remove the products at the end of the program and allow to cool down.
- 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.
- Loading of sterilizer according to manufacturer's instructions follow manufacturer's operating instructions

**STORAGE**

The device should be stored in the sterilization pouch (or instrument block) until required.







**TRACEABILITY**

Each package includes **Lot number** LOT on its label.



This number must be quoted in any correspondence regarding to the product.

**Symbols Interpretation**

Symbols on the product package should be interpreted as follows:

	Catalogue number / Part Number (P/N)
	Batch code/number
	Manufacturer
	Consult Instruction for use
	Non-Sterile Product
	Keep Dry
RxOnly	(ref US FDA CDRH) DEVICE for professional use only

**CONTACT INFORMATION**

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