

Hasharon Dental Instructions for Reprocessing *Non-Sterile* - Dental Polishers

DESCRIPTION

Hasharon Dental polishers consist of synthetic/silicone rubber, pigments and abrasive, the shanks are made of stainless steel. The Dental polishers are part of Hasharon Dental Rotary instruments portfolio available to the clients including diamond coated burs, discs and tungsten carbide burs.

The dental polishers are provided non-sterile (multi-use)



SCOPE

These instructions are applicable to the cleaning of the multi-use dental polishers prior to initial use, and there after every subsequent re-use. The multi-use dental polishers are supplied mechanically clean, but NOT sterile. For reprocessing instruction for the diamond coated burs/discs or the Tungsten Carbide burs please follow their specific instruction provided separately.

INDICATIONS FOR USE

The products prescribed are used by dentists in dental clinics and hospitals for dental and periodontal applications. The Rotary Instruments can be used to cut or polish a wide variety of materials, including enamel, dentine and bone, amalgam, composite, glass-ionomer cements, polymer/ceramic veneers, zirconia and precious/non-precious metals. Therefore, they are also being used in dental laboratories in addition to the actual clinical use in the patient mouth or chair-side. The Rotary instrument pattern/type is selected in order to cut/grind/polish a specific material in a specific application.

Professional use - Dental Rotary Instruments are intended for dentistry and must only be used by dentists and other qualified professionals who are familiar with use of these instruments and its reprocessing procedures based on their training and experience. Therefore, user training is not needed to ensure specified performance, safe use and reprocessing of the medical device.

- a) Used Dental Polishers shall be considered as contaminated and as such, appropriate precautions shall be taken during re-processing and disposal. Suitable eye protection, gloves and a mask should be worn when re-processing.
- b) In the event of dental polishers being returned to **Hasharon Dental**, please ensure any contaminated and/or potentially contaminated burs have been effectively cleaned and sterilized and are appropriately packaged for return.

STORAGE (pre-use): Store in a dry and clean environment at ambient temperature.

GENERAL PRECAUTIONS - PLEASE READ CAREFULLY

- a) The device is to be used as per the following instructions by physician or licensed practitioner.
- b) Carefully read package labels to ensure appropriate use of the device. Failure to do so may cause procedural delays or patient or user injury.
- c) Failure to follow these instructions can result in cross-contamination that may lead to infection for the patient/user.
- d) Clean and sterilize the device supplied in a non-sterile condition in accordance with the directions below before initial use and after each subsequent use to avoid any risk of contamination.
- e) Wear gloves, mask and eye protecting gear when handling contaminated instruments.
- f) Prior to use inspect the device for broken and/or damaged flutes, rust, or any other visible damage. Discard any potentially defective instrument. Do not use worn- out or dull devices.
- g) Observe the manufacturer's reprocessing materials information in order to ensure material compatibilities for cleaning, disinfection and sterilization
- h) The reprocessing materials exposure time and concentration specified by the manufacturer must be followed.
- i) Ultrasonic bath must not exceed temperatures of 42 °C because of the possible coagulation of protein
- j) 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.
- k) Strong acids and strong bases may oxidize the stainless-steel shank.
- l) Instructions of cleaning and/or disinfecting solutions must specifically state "suitable for rubber polishers or synthetics/silicones ."

REPROCESSING INSTRUCTIONS FOR DENTAL POLISHERS

SCOPE

The reprocessing instructions detailed below apply only to reusable dental Polishers. Polishers shall be reprocessed prior to being reused and upon initial use.

LIMITATIONS OF RE-USE

Reprocessing will have little effect on **Hasharon Dental** 's dental polishers. The end of the device life is determined by wear and damage in use and the device should be inspected for defects during the preliminary cleaning process.

Delay between use and reprocessing must be kept to a minimum to avoid contaminants drying, thereby making cleaning more difficult. Therefore, keep the unclean instruments immersed in the cleaning/disinfecting agent in accordance with manufacturer instructions, but in any event, do not exceed 12 hours.

Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided.

Caution: Do not leave instruments immersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the polishers have been thoroughly cleaned first.

WARNINGS

Used instruments 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 instruments are also considered as bio-hazard and need to be discarded as bio-hazard waste unless reprocessing procedures has been done in accordance with these instructions.

PREPARATION FOR CLEANING	There are no special requirements unless local infection controls require the use of a disinfectant immediately after use, in which case the selected disinfectant must be validated by the user for cleaning dental polishers shall be used and the manufacturer’s instructions followed.
PRE-TREATMENT	Pre-clean under running water with a brush directly after use. 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).
MANUAL CLEANING,	If manual cleaning is implemented, the instruments should be cleaned in a sink reserved for the purpose. Note: Coarse surface contamination on the instruments must be removed before manual reprocessing (see pre-treatment) 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.
MANUAL DISINFECTION	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.
AUTOMATED CLEANING AND DISINFECTING	Note: Coarse surface contamination on the instruments must be removed prior to automatic Reprocessing (see pre-treatment) 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, reclean medical devices again manually. Subsequently, the recleaned medical devices must again be reprocessed automatically.				
INSPECTION	All instruments must be inspected visually for cleanliness, integrity and functionality, if necessary, by using an illuminated magnifying glass (3-6 diopters). All instruments are to be checked for damage and wear. Damaged medical devices may no longer be used and must be sorted out.			

STERILIZATION - USING STEAM

SCOPE

These sterilization instructions applicable to dental polishers initially provided non-sterile and to non-sterile dental polishers that are being reused. No sterilization before first use is required for instruments labeled '**Sterile**'.

PACKAGING FOR STERILIZATION	<p>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.</p> <p>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.</p>
STEAM STERILIZATION	<p>Follow the autoclave manufacturer's instructions to sterilize the instrument. In particular, care must be taken not to exceed the maximum recommended load for the autoclave.</p> <p>Device: Sterilizer according to DIN EN 285 or small steam sterilizer according to DIN EN 13060, type B process</p> <p>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.</p> <ol style="list-style-type: none"> 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. <p>NOTE: Local infection control practice may recommend a different combination of holding time and temperature.</p>
STORAGE	<p>The dental polishers should be stored in their sterilized pouch and protected from recontamination in proven suitable sterile packaging, cassettes or retainers until required.</p> <p>Pouches must be dried before opening to avoid recontamination of the contents with water.</p> <p>Storage should be in dry, clean conditions and at ambient temperature</p> <p>Duration of storage according to own specifications.</p>

VALIDATION OF CLEANING AND STEAM STERILIZATION








The above detailed processes *have been validated* as being capable of preparing Hasharon Dental's polishers for reuse. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed, using the equipment, materials and personnel in the reprocessing facility, achieve the required results. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

TRACEABILITY



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

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

GLOSSARY OF SYMBOLS

REF	Catalogue number / Part Number (P/N)
LOT	Batch code/number
	Manufacturer
	Date of manufacturing
	Consult Instruction for use
	Non-Sterile Product
	Keep Dry
MD	Medical Device
	Wear mask and eye protection gear while operating
	Maximum speed
RxOnly	(ref US FDA CDRH) DEVICE for professional use only

CONTACT INFORMATION

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