

Hasharon Dental
Instructions for Reprocessing *Non-Sterile* - Dental Diamond burs/discs

DESCRIPTION

Hasharon Dental Diamond Dental Burs/Discs are manufactured from stainless steel coated with Diamond. The Diamond burs/disc are part of Hasharon Dental Rotary instruments portfolio available to the clients including dental polishers and tungsten carbide dental burs.

The dental diamond burs/discs are provided non-sterile (multi-use)



SCOPE

These instructions are applicable to the cleaning of the multi-use Diamond Dental Burs/Discs prior to initial use, and there after every subsequent re-use. The multi-use Diamond Dental Burs/Discs are supplied mechanically clean, but NOT sterile. For reprocessing instruction for the dental polishers or the Tungsten Carbide dental 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 burs/discs 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 burs/discs 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 or 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) 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.
- j) Strong acids and strong bases may oxidize the stainless-steel shank.

REPROCESSING INSTRUCTIONS FOR DIAMOND DENTAL BURS/DISCS

SCOPE

The reprocessing instructions detailed below apply only to reusable burs/discs. Burs/discs 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 rotary instruments. 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 device 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 device immersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the burs have been thoroughly cleaned first.

WARNINGS

Used devices 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 devices 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 burs/discs shall be used and the manufacturer’s instructions followed.
MANUAL CLEANING, DRYING AND INSPECTION PROCEDURE	<p>If manual cleaning is implemented, the instruments should be cleaned in a sink reserved for the purpose. Pre-clean under running water with a brush directly after use.</p> <ol style="list-style-type: none"> 1) Rinse the instruments under running cold water for at least 1 minute. then, keeping them immersed, brush thoroughly away from the body particularly at the difficult to access points (grooves, bristles, holes, rough surfaces). Soak in a neutral cleaning or cleaning/disinfecting agent labeled for use on dental rotary instruments or other similar types of reusable medical instruments, following the agent manufacturer’s instructions. 2) Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. 3) Wire brushes must be used with caution, as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel. 4) After cleaning, inspect the instrument, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary. 5) Dry the instruments using paper toweling or dry heat not exceeding 140°C. 6) Inspect the instruments, with the aid of magnification if necessary to ensure that all contaminations has been removed. Repeat the cleaning process if necessary and discard any damaged or corroded instruments. <p>Note: surface contamination on the burs must be removed prior to automatic reprocessing</p>
AUTOMATED CLEANING	<p>PRE-CLEANING –</p> <ol style="list-style-type: none"> 1) Prepare a 0.1% neutral/mild pH enzymatic detergent, according to manufacturer’s instructions. 2) Rinse the instrument under running tap water for at least one (1) minute. 3) Soak the instruments immediately into detergent solution, for two (2) minutes. 4) Scrub the instrument under running water with soft nylon brush to remove any remaining blood or debris for at least one (1) minute. 5) Place them on a clean cloth to avoid any contact between them during the next cleaning procedure

	<p>AUTOMATED CLEANING PROCEDURE – Place the instruments in the washer in a suitable small parts tray or on the load carrier such that all surfaces of the instruments will be cleaned and disinfected. The product was validated using: Washer/disinfector Miele PROFESSIONAL, 1/248</p> <ol style="list-style-type: none"> 1) Run the automatic wash cycle – Short cycle parameters 2) Two (2) Minutes prewash at 30±5°C (86±41°F) with tap water. 3) Two (2) Minutes prewash at 30±5°C (86±41°F) with tap water. 4) Ten (10) Minutes main wash with natural pH detergent and tap water at 25±5°C (110±41°F). 5) One (1) Minute rinse with tap water at 30°C (86°F) 6) Ten (10) Minutes distilled water rinse at 30°C (86°F) 7) Twenty (20) Minutes air drying phase at high temperature of 100°C (414°F) <p>** Hasharon Dental validated the cleaning process with short automatic wash cycle. Any cleaning and disinfecting agents used must be compatible with dental instruments; otherwise accelerated corrosion or other damage may occur. The washer disinfector and the cleaning agent manufacturers' instructions must be followed.</p> <p>POST AUTOMATED CLEANING PROCEDURE –</p> <ol style="list-style-type: none"> 1) Remove the instruments at the end of the washer programme. 2) Check that the load is dry and, if necessary, dry with medical compressed air. 3) Visually inspect the instruments for cleanliness. If contamination is still visible, reclean them again manually. 4) Subsequently, the recleaned instruments must be reprocessed again automatically before sterilization 5) All instruments must be inspected visually for cleanliness, integrity and functionality, if necessary, by using an illuminated magnifying glass 6) All instruments are to be checked for damage and wear. Damaged medical devices may no longer be used and must be sorted out
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STERILIZATION - USING STEAM

SCOPE

These sterilization instructions applicable to burs/discs initially provided non-sterile and to non-sterile burs/discs that are being reused. No sterilization before first use is required only for burs labeled 'Sterile'.

PACKAGING FOR STERILIZATION	<p>If using an autoclave with a pre-vacuum cycle, pack the instruments in appropriate instrument pouches validated for steam sterilization.</p> <p><i>NOTE: Local legislation for sterilization may require that burs are wrapped in pouches for processing in either type of autoclave.</i></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>Hasharon Dental has validated steam sterilization in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time, temperature and drying time as specified in the table below. The minimum holding time is the minimum time for which the minimum temperature is sustained.</p> <ol style="list-style-type: none"> 1) Individually package each item in a sterilization pouch 2) Place the packaged products in the sterilization chamber 3) Start the program <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>instrument</th> <th>Cycle duration minutes minimum (Min.)</th> <th>Cycle duration minutes maximum (Min.)</th> <th>Cycle temperature (°C)</th> <th>Drying time (Min.)¹</th> </tr> </thead> <tbody> <tr> <td>Diamond burs</td> <td>3</td> <td>6</td> <td>134 °C</td> <td>30</td> </tr> <tr> <td>Diamond discs</td> <td>5</td> <td>10</td> <td>135 °C</td> <td>30</td> </tr> </tbody> </table> <p>¹Ensure the minimum drying time is not compromised as failure to achieve this could result in a build-up moisture and the burs corroding.</p>	instrument	Cycle duration minutes minimum (Min.)	Cycle duration minutes maximum (Min.)	Cycle temperature (°C)	Drying time (Min.) ¹	Diamond burs	3	6	134 °C	30	Diamond discs	5	10	135 °C	30
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	<p>4) Remove the instruments at the end of the program and allow to cool down</p> <p>5) check the packaging for possible damage and screening effects</p> <p>6) Faulted packaging must be inspected as being non-sterile. The instruments must be repacked and re-sterilized.</p> <p>NOTE: Local infection control practice may recommend a different combination of holding time and temperature.</p>
STORAGE	<p>The instruments should be stored in their sterilized pouches until required for use.</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>












VALIDATION OF CLEANING AND STEAM STERILIZATION

The above detailed processes *have been validated* as being capable of preparing **Hasharon Dental's** burs/discs 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

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

CONTACT INFORMATION

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