


Instruction for Use – Non Sterile Multi-Use Diamond Dental Burs

Description

Hasharon Dental Diamond Dental Burs are manufactured from stainless steel coated with Diamond

The burs are provided sterile or non-sterile 

SCOPE

These instructions are applicable to the cleaning of the Diamond Dental Burs prior to initial use, and there after every subsequent re-use. Diamond Dental Burs are supplied mechanically clean, but NOT sterile.

INDICATIONS FOR USE

Hasharon Dental Diamond burs can be used for a wide variety of restorative procedures including but not limited to: removal of caries or old restorations, preparation of cavities for restoration, finishing of restorations, preparation of crowns, orthodontic device procedure and any other dental operation. The bur pattern to be selected for specific application. For best product performance, always match the bur to the task to be performed.

CONTRAINDICATIONS For the use of **Hasharon Dental** Diamond burs is contraindicated on any patient who is allergic to any of the components of the product.

- a) Used burs 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 being returned to **Hasharon Dental**, please ensure any contaminated and/or potentially contaminated burs have been effectively cleaned and are appropriately packaged for return.

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

CLINICAL PRECAUTIONS AND WARNINGS:

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 use of the appropriate device. Failure to do so may cause procedural delays or patient or user injury.
- c) Failure to follow these instructions may cause the following: preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the diamond burs.
- d) Clean and sterilize the burs supplied in a non-sterile condition in accordance with the directions below before first use and before each reuse to avoid any risk of contamination.
- e) Always wear gloves when handling contaminated instruments.
- f) Protect patient's eyes and vulnerable tissues when using these diamond burs.
- g) Clinicians should wear eye protection and facemask when using diamond burs.

- h) Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- i) Ensure the bur is fully seated and gripped in the handpiece collet to. Failure to follow these instructions may cause preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the burs.
- j) Prior to use inspect the bur for broken and/or damaged flutes, discard any potentially defective burs. Do not use worn- out or dull devices.
- k) Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to procedural delays or injury of the patient or user, aspiration or swallowing of the device or damage to the preparation site due to vibration of a worn chuck or turbine.
- l) Discard any damaged diamond burs immediately.
- m) Do not use rusted burs.
- m) Read carefully the labels on the bur package.
- n) Before use, run the handpiece to check for any abnormalities including overheating.
- p) Do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to fail.
- q) Move the bur continuously when in use to avoid localized heating and/or damage to the bur. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- r) Avoid removing the bur at too sharp angle to avoid leverage and breakage which could cause patient or user injury.
- s) Never force a bur into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- t) Never exceed the maximum speeds as shown in the table as this may generate undesirable heat.
- u) When using short burs (up to 20 mm in length) make certain the head/diamonds do not come in contact with the chucking mechanism
- v) Pediatric **Mini-Diamonds** Burs (short) should be used with mini handpiece intended for use with short shank burs and normal burs up to 20 mm in length

The bur pattern selected will be chosen to cut a specific material in a specific application. The following table gives guidance and **provides recommended RPM**

Instrument head diameter 1/10 mm	Maximum permissible speed (RPM)	Recommended operational speed (RPM)
007 - 010	450,000	100,000 - 220,000
011 - 014	450,000	70,000 - 220,000
015 - 018	450,000	55,000 - 160,000
019 - 023	300,000	40,000 - 120,000
024- 027	160,000	35,000 - 110,000
028 - 031	140,000	30,000 - 95,000
032 - 040	120,000	25,000 - 75,000
041 - 054	95,000	15,000 - 60,000
055 - 070	60,000	12,000 - 40,000
080 - 100	45,000	10,000 - 20,000

Reprocessing Instructions For Diamond Dental Burs

SCOPE

The reprocessing instructions detailed below apply only to reusable burs. Burs shall be reprocessed prior to being reused.

LIMITATIONS OF RE-USE

Reprocessing will have little effect on Hasharon Dental's dental burs. The end of bur's life is determined by wear and damage in use and the burs 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 burs immersed in the cleaning/disinfecting agent in accordance with manufacturer instructions, but in any event, do not exceed 12 hours.

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

WARNINGS

Used burs 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 burs are also considered as bio-hazard and need to be discarded as bio-hazard waste unless reprocessing procedures has been done according the above instructions.

<p>PREPARATION FOR CLEANING</p>	<p>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 shall be used and the manufacturer's instructions followed.</p>
<p>MANUAL CLEANING, DRYING AND INSPECTION PROCEDURE</p>	<p>If manual cleaning is implemented, the burs should be cleaned in a sink reserved for the purpose.</p> <p>Pre-clean under running water with a brush directly after use.</p> <ol style="list-style-type: none"> 1) Rinse the burs under running cold water and, keeping them immersed, brush thoroughly away from the body using a neutral cleaning or cleaning/disinfecting agent labeled for use on dental burs 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 burs, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

	<p>5) Dry the burs using paper toweling or dry heat not exceeding 140°C.</p> <p>6) Inspect the burs, with the aid of magnification if necessary and discard any damaged or corroded instruments.</p> <p>Note: surface contamination on the burs must be removed prior to automatic reprocessing</p>
<p>AUTOMATED CLEANING</p>	<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. (in the lowest recommended concentrations). 2) Rinse the bur under running tap water for at least one (1) min. 3) Soak burs immediately into detergent solution, for two (2) minutes. 4) Scrub the burs under running water with soft nylon brush to remove any remaining blood or debris for at least one (1) minute. 5) Place the burs on a clean cloth to avoid any contact between them during the next cleaning procedure <p>AUTOMATED CLEANING PROCEDURE -</p> <p>Place the burs 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.</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 cleansing and disinfecting agents used must be compatible with dental burs; otherwise accelerated corrosion or other damage may occur. The washer disinfectant 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 burs for cleanliness. If contamination is still visible, reclean the burs again manually. 4) Subsequently, the recleaned burs 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

STERILIZATION - USING STEAM

SCOPE

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

<p>PACKAGING FOR STERILIZATION</p>	<p>If using an autoclave with a pre-vacuum cycle, pack the burs in appropriate instrument trays or pouches validated for steam sterilization.</p> <p>If using an autoclave without a pre-vacuum cycle, the burs should not be packed or wrapped but should be contained in appropriate bur stands with perforated lids.</p> <p>NOTE: Local legislation for sterilization may require that burs are wrapped in pouches for processing in either type of autoclave.</p>								
<p>STERILIZATION</p>	<p>Follow the autoclave manufacturer's instructions to sterilize the burs. 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 of 3 minutes minimum and six minutes maximum at a temperature of 134 °C and drying time of 30 Min.</p> <p>The holding time is the minimum time for which the minimum temperature is sustained.</p> <ol style="list-style-type: none"> 1) Place the packaged products in the sterilization chamber 2) Start the programme <table border="1" data-bbox="651 1205 1312 1299"> <thead> <tr> <th>Cycle duration minutes minimum (Min.)</th> <th>Cycle duration minutes maximum (Min.)</th> <th>Cycle temperature (°C)</th> <th>Drying time (Min.)</th> </tr> </thead> <tbody> <tr> <td>3</td> <td>6</td> <td>134 °C</td> <td>30</td> </tr> </tbody> </table> <ol style="list-style-type: none"> 3) Remove the burs at the end of the programme and allow to cool down 4) check the packaging for possible damage and screening effects 5) Faulted packaging must be inspected as being non-sterile. The instruments must be repacked and re-sterilized. <p>NOTE: Local infection control practice may recommend a different combination of holding time and temperature</p>	Cycle duration minutes minimum (Min.)	Cycle duration minutes maximum (Min.)	Cycle temperature (°C)	Drying time (Min.)	3	6	134 °C	30
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<p>STORAGE</p>	<p>The burs should be stored in the sterilization container (bur stand or pouch) until required.</p> <p>Containers or 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 to prepare **Hasharon Dental's** dental burs for reuse. It remains the responsibility of the user 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
	Consult Instruction for use
	Non-Sterile Product
	Keep Dry
	(ref US FDA CDRH) DEVICE for professional use only

CONTACT INFORMATION

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