


Hasharon Dental Center 'Sterile' Single Use Diamond Dental Burs IFU - Instructions for Use

DESCRIPTION

Diamond dental burs are made of a single piece of hardened stainless steel, coated with diamonds, for dental clinic applications. The burs are provided sterile or non-sterile.

Burs that are labeled as '*Sterile*' are packed in a dedicated cleanroom facility and sterilized using

Gamma Irradiation. 

These burs are labeled as single-use devices and should NOT be reused or re-processed



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) Always wear gloves when handling contaminated instruments.

- e) Protect patient's eyes and vulnerable tissues when using these diamond burs.
- f) Clinicians should wear eye protection and facemask when using diamond burs.
- g) Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- h) 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.
- i) 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.
- j) 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.
- k) Discard any damaged diamond burs immediately.
- l) 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

STERILE PRODUCT SHELF-LIFE













- On the provision that appropriate storage and handling practices are applied to all unopened pouches, product sterility will be maintained for five (5) years unless sterile package is opened or damaged.
- **Do-not** use the product if the package is opened or damaged. 
- Sterile provided products are labeled with their expiry date. **Do-not** use the products after their stated expiration date 
- Storage should be in dry, clean condition and at ambient temperature.

TRACEABILITY

Each package includes **Lot number**  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
	Do not Re-use
	Do not re-sterilize
	Sterilized using irradiation
	Do not use if package is damaged
	Date of Manufacture
	Use by Date
	Keep Dry
	(ref US FDA CDRH) DEVICE for professional use only

CONTACT INFORMATION

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