

Hasharon Dental Multi-Use Diamond HP Dental Burs & Discs **Instruction for use**

Description:

The diamond discs and HP burs family includes HP burs / laboratory burs and dental diamond discs. A diamond dental disc or HP burs are a rotary abrading device made of stainless steel which is coated with diamond particles on the working end and which is designed to fit into a dental handpiece. The diamond discs and HP burs are provided non-sterile and can be reused, therefore read the following cleaning and sterilization instructions carefully.

PRECAUTIONS:

- The dental rotary instrument is intended for laboratory and dental applications in dental clinics and hospitals by licensed dentist (except for laboratory applications, where the instrument is used by licensed technician). **Rx only**.
- **Clean and sterilize** instruments in accordance with the directions below before first use and before each reuse
- **For dental use in mouth of dental discs, use shield protection!**
- Always wear gloves when handling contaminated instruments.
- Eye protection must be worn to protect against ejected particles.
- Surgical masks must be worn to avoid inhalation of aerosol or dust generated.
- Ensure that the instruments are securely gripped in the handpiece collet.
- Before each use, inspect the disc for damaged or excessive wear. Discard worn device.
- Do not use rust instruments
- Maintain handpieces in good working order and correctly lubricated.
- Do not apply excessive pressure on the device
- Avoid using the device at too high an angle to avoid leverage and breakage.
- **Move the device continuously** when in use to avoid localized heating and/or damage to the Device.

APPLICATIONS:

A diamond dental disc or HP burs is a rotary abrading device made of stainless steel which is coated with diamond particles on the working end and which is designed to fit into a dental handpiece. The handpiece connection provides the rotation, allowing the user to abrade hard structures like teeth, bone and metal, plastics, porcelains and similar materials. The diamond discs are used by dentists in dental clinics/hospitals/labs for the removal of small amounts of outer enamel tooth surface between two adjacent teeth (Interproximal reduction). It is a means to acquire additional space to create ideal tooth alignment.

Guidance for RPM:

| Instrument head diameter 01/10(mm) - ISO | Maximum permissible speed |
|--|---------------------------|
| | (RPM) |
| HP Burs | |
| 007 - 046 | 50,000 |
| 047 - 049 | 45,000 |
| 050 - 054 | 40,000 |
| 055 - 064 | 35,000 |
| 065 - 074 | 30,000 |
| 075 - 094 | 25,000 |
| 095 - 119 | 20,000 |
| 120 - 139 | 18,000 |
| 140 - 159 | 16,000 |
| 160 - 179 | 14,000 |
| 180 - 199 | 12,000 |
| 200 - 220 | 10,000 |
| Dental Discs | |
| 100 - 127 | 30,000 |
| 130 - 300 | 25,000 |

REPROCESSING INSTRUCTIONS FOR DENTAL ROTARY INSTRUMENTS

LIMITATIONS OF RE-USE

Reprocessing will have little effect on Hasharon Dental diamond dental burs/discs. The end of bur's/disc's life is determined by wear and damage in use and the burs/discs should be inspected for defects during the preliminary cleaning process.

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

Caution: Do **not** leave burs/discs 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 dental burs/discs are consider as bio-hazard and need to discard as bio-hazard waste unless reprocessing instruction has been done

CLEANING, DRYING AND INSPECTION PROCEDURE

MANUAL CLEANING:

If manual cleaning is implemented, the burs/discs should be cleaned in a sink dedicated for the purpose. Hasharon Dental has validated the procedure detailed below:

- 1) **Rinse** the instruments 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/discs 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 instruments, preferably with the aid of magnification, 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) After cleaning, **inspect** the instruments, preferably with the aid of magnification, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

STERILIZATION USING STEAM

SCOPE

These sterilization instructions are applicable to HP burs/discs initially provided **non-sterile** and to **non-sterile** burs that are about to be **reused**.

PACKAGING FOR STERILIZATION

If using an autoclave with a pre-vacuum cycle, pack the burs/discs in dedicated instrument trays or pouches validated for steam sterilization.

If using an autoclave without a pre-vacuum cycle, the burs/discs should not be packed or wrapped but should be contained in dedicated bur/disc stands with perforated lids.

***NOTE:** Local legislation may require that burs/discs will be wrapped in pouches for processing in either type of autoclave.*

STERILIZATION PROCESS

Follow the autoclave manufacturer's instructions to sterilize the burs/discs. In particular, care must be taken not to exceed the maximum recommended load for the autoclave.

Hasharon Dental has validated steam sterilization in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of 10 minutes at a temperature of 135 °C and 30 minutes drying. The holding time is the **minimum time** for which the minimum temperature is sustained.

***NOTE:** Local infection control practice may recommend a different combination of holding time and temperature.*


STORAGE

The burs/discs should be stored in the sterilization container (bur/disc stand or pouch) until use. Containers or pouches must be dried before opening to avoid recontamination of the contents with water. Storage should be in dry, clean conditions and at ambient temperature.

VALIDATION OF CLEANING AND STEAM STERILIZATION









The above detailed processes have been validated as being Hasharon Dental recommended process for preparing Hasharon Dental 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. This may require validation and monitoring of the process. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

TRACEABILITY


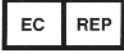
Each package bears **Lot number**  on its label. This number must be quoted in any correspondence regarding to the product.

SYMBOLS INTERPRETATION

Symbols on the product package should be interpreted as follows:

| | | | |
|---|---|---|---|
|  | Consult operating instructions; |  | Manufacturer |
|  | Catalogue number / Part Number (P/N) |  | Batch code/number |
|  | Authorized Representative in the European Community |  | CE-Mark Symbol |
|  | Non-Sterile Product |  | Prescription device for professional use only |

CONTACT INFORMATION

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