

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

DESCRIPTION


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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

SAFETY IN USE –

Read precautions carefully:

The device is to be used as per the following instructions by physician or licensed practitioner.



RxOnly

- Always wear gloves when handling contaminated instruments.
- Eye protection must be worn to protect against ejected particles.
- Do not use 'sterile' labeled burs if package is opened or damaged.
- Surgical masks must be worn to avoid inhalation of aerosol or dust generated.
- Ensure that the bur is securely gripped in the handpiece collet.
- Do not use worn-out burs.
- Maintain handpiece in good working order and correctly lubricated.
- Do not exceed the maximum speeds tabulated in this leaflet.
- Do not apply excessive pressure on the bur.
- Avoid removing the bur at too sharp an angle to avoid leverage and breakage.
- Move the bur continuously when in use to avoid localized heating and/or damage to the bur.
- Do not reuse.
- Read carefully the labels on the packaging.


DIAMOND BURS - guidance for maximum 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 













TRACEABILITY

Each package includes **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:

	<i>Do not re-use</i>		<i>Do not re-sterilize</i>
	Consult operating instructions;		Manufacturer
	Catalogue number / Part Number (P/N)		<i>Sterilized using irradiation</i>
	Batch code/number		Use-by date (expiry date)
	Authorized Representative in the European Community		Do not use if package is open or damaged
	CE-Mark Symbol		Prescription device

CONTACT INFORMATION



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