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Rotary Instruments: Dental Diamond Burs **IFU – Instructions for Use**

1. Intended Use, Users, Patients, and Environment

- DEM's Dental Diamond Bur is an abrasive device used to remove, reduce, smooth or shape tooth surfaces during dental procedures.
- This device must only be used by qualified dental personnel. Rx.
- The Device is indicated for patients who need to undergo dental procedure treatment, which requires an efficient Dental bur during the reduction, smoothing, or shaping of tooth surfaces during dental procedures.
- This device must only be used in hospital environments, clinics or dental offices.

2. Warnings

- 2.1. Read all instructions before operating this device. The manufacturer accepts no liability for any damage resulting from improper use of this device and / or for any purpose other than those covered by these instructions.
- 2.2. This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.
- 2.3. Do not use DEM's Dental Diamond Burs as levers and / or at incorrect angulations.

3. Safety In Use

- 3.1. The device is to be used on the instruction of and by a physician or licensed practitioner. Rx only.
- 3.2. Clean and sterilise burs in accordance with the directions below before first use, and before each reuse.
- 3.3. Always wear gloves when handling contaminated instruments.
- 3.4. Eye protection must be worn to protect against ejected particles.
- 3.5. Surgical masks must be worn to avoid inhalation of aerosol or dust generated.
- 3.6. Ensure that the bur is securely gripped in the handpiece collet.
- 3.7. Do not use worn-out burs.
- 3.8. Maintain handpieces in good working order and correctly lubricated.
- 3.9. Do not apply excessive pressure on the bur.
- 3.10. Avoid removing the bur at too sharp an angle to avoid leverage and breakage.

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4. 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	60,000	12,000 - 40,000

5. Containment at The Point of Use

- 5.1. Keep the unclean burs immersed in the cleaning / disinfecting agent in accordance with its manufacturer instructions, but in any event do not exceed 12 hours.
- 5.2. 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.

6. Cleaning, Drying And Inspection Procedure

6.1. Manual Cleaning:

- 6.1.1. Rinse the burs under running cold water and, keeping them immersed, brush thoroughly away from the body using a neutral cleaning fluid.
- 6.1.2. After cleaning, inspect the burs, preferably with the aid of magnification, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.
- 6.1.3. Dry the burs using paper toweling or dry heat not exceeding 140°C.

6.2. Automated Cleaning:

- 6.2.1. Any cleansing and disinfecting agents used must be compatible with the materials used in the dental burs.
- 6.2.2. The washer disinfectant and the cleaning agent manufacturers' instructions must be followed.
- 6.2.3. After cleaning, inspect the burs, preferably with the aid of magnification, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

6.3. In-Clinic Sterilisation

- 6.3.1. Follow the autoclave manufacturer's instructions to sterilise the burs.
- 6.3.2. Autoclave the burs for a minimum of 6 min at temperature of 134°C.

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6.4. In-Clinic Storage

6.4.1. The burs should be stored in a dry sterilisation container (bur stand or pouch) until required. Storage should be in dry, clean conditions and at ambient temperature.

6.5. Other Notes

- 6.5.1. Use sterilising and cleaning devices and materials according to the manufacturer's recommended procedure.
- 6.5.2. It is the responsibility of the user to ensure that sterilisation is effective.

Manufactured by:



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