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## Dental Diamond Burs

### IFU – Instructions for Use

#### 1. Intended Use, Users, Patients, and Environment

- Romidan's Dental Diamond Bur is an abrasive device used for 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 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 Romidan'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 physician or licensed practitioner. Rx only.
- 3.2. Clean and sterilize 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

#### 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



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## 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.
- 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. In Clinic Sterilization

- 6.2.1. Follow the autoclave manufacturer's instructions to sterilize the burs.
- 6.2.2. Autoclave the bars for a minimum of 6 min at temperature of 134°C.

### 6.3. In Clinic Storage

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

### 6.4. Other Notes

- 6.4.1. Use sterilizing and cleaning devices and materials according to the manufacturers recommended procedure.
- 6.4.2. It is the responsibility of the user to ensure that sterilization is effective

#### Manufactured by:



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