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 :

<table>
<thead>
<tr>
<th>Instrument head diameter (1/10 mm)</th>
<th>Maximum permissible speed (RPM)</th>
<th>Recommended operational speed (RPM)</th>
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</thead>
<tbody>
<tr>
<td>007 - 010</td>
<td>450,000</td>
<td>100,000 - 220,000</td>
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<tr>
<td>011 - 014</td>
<td>450,000</td>
<td>70,000 - 220,000</td>
</tr>
<tr>
<td>015 - 018</td>
<td>450,000</td>
<td>55,000 - 160,000</td>
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<tr>
<td>019 - 023</td>
<td>300,000</td>
<td>40,000 - 120,000</td>
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<tr>
<td>024 - 027</td>
<td>160,000</td>
<td>35,000 - 110,000</td>
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<tr>
<td>028 - 031</td>
<td>140,000</td>
<td>30,000 - 95,000</td>
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<tr>
<td>032 - 040</td>
<td>120,000</td>
<td>25,000 - 75,000</td>
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<tr>
<td>041 - 054</td>
<td>95,000</td>
<td>15,000 - 60,000</td>
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<tr>
<td>055</td>
<td>60,000</td>
<td>12,000 - 40,000</td>
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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 140ºC.

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 134ºC.

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.