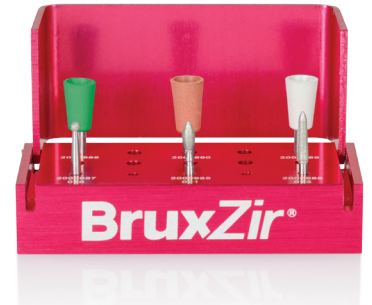


BruxZir™ Adjustment & Polishing Kit

Instructions for Use

CAUTION: Federal U.S. law restricts this device to sale by or on the order of a licensed dentist or physician.

IMPORTANT: PLEASE READ



1. Product Description

The burs are made of a single piece of hardened stainless steel, coated with diamonds, for dental clinic applications.

2. Indications for Use

The burs are rotary dental instruments powered by handpieces which are used to remove decay, prepare teeth for restorations, and trim and polish restorations.

3. Sterilization

(Instruments are shipped non-sterile)

Autoclave the instruments for a holding time not less than three (3) minutes at a minimum temperature range of 134 °C and 137 °C.

- If using a **vacuum autoclave**, pack the burs in dedicated bur stands or pouches validated for sterilization.
- If using a **non-vacuum autoclave**, the burs should not be packed or wrapped but be contained in dedicated bur stands with perforated lids.

4. Storage and Handling

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

Inspect the burs under magnification, if necessary, and discard any instruments that are damaged or corroded.

5. WARNINGS

Maintain constant movement when relieving material with an active bur. Do NOT hold the bur stationary in a single location, as heat-related damage may result.

Used burs should be considered contaminated, and appropriate handling precautions should be taken during reprocessing. Additional precautionary measures may be required if there are specific infection or cross-contamination risks from the patient.

6. Precautions

- The device is to be used on the instruction of and by a dentist or licensed practitioner.
- Always wear gloves when handling instruments.
- Eye protection must be worn to shield against ejected particles.
- Do NOT use the burs if package is open or damaged. Clean and sterilize them before use.
- Surgical mask must be worn to avoid inhalation of any aerosol or dust generated.
- Ensure that the bur is securely gripped in the handpiece collet.
- Do NOT use worn-out burs.
- Handpieces should be sufficiently lubricated and maintained in good working order.
- Do NOT exceed the maximum speed of 20,000 rpm for polishing cups.
- Do NOT apply excessive pressure on the bur.
- Avoid removing the bur at an excessive angle, to avoid leverage and breakage.
- Move the bur continuously when in use to avoid localized heating and/or damage to the bur.

7. NOTE

It is the responsibility of the dentist to ensure that sterilization is effective.

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See instructions for use



Lot/Batch Number



Not Sterile Product

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2212 Dupont Dr • Irvine, CA 92612

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