

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 kit contains burs, cups and discs designed to adjust and/or trim and polish BruxZir® Restorations, as needed, prior to final seating.

2. Indications for Use

Burs, cups and discs are rotary dental instruments powered by handpieces. Burs are used to trim and polish restorations. Polishing cups and discs are used to polish restorations.

3. Ultrasonic Cleaning

Do not use ultrasonic solutions containing alkali products such as sodium hydroxide or potassium hydroxide.

- Always mix solutions according to instructions.
- A five-minute cycle time is recommended.
- Remove the burs from ultrasonic solution and rinse well with water.
- Dry the bur block thoroughly before placing it in a sterilization pouch.

4. Sterilization (Autoclave)

(Instruments are shipped non-sterile)

Operate the sterilizer unit at a minimum of 121°C for 30 minutes or at 132°C for 15 minutes with steam pressure of 15 psi. Allow sterilized components to dry for 15-30 minutes. Larger loads will require an additional 5-15 minutes.

- 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.

5. 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.

6. 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.

7. Uses for Burs, Polishing Cups and Discs

- The round bur is used for adjusting fossae.
- The tapered bur is most effective for adjusting cusps or proximal contacts.
- The football-shaped bur is most effective for adjusting the occlusal surfaces of posterior teeth and lingual surfaces of anterior teeth.
- The green cup can be used to remove abrasions. Use light pressure and no water to pre-polish with the green cup. The green cup can be used alone for minor adjustments.
- The brown cup can be used to achieve a more glossy look on the adjustment areas.
- The white cup can be used with light to medium pressure to achieve a “wet” high shine.
- The brown pre-polishing disc can gently remove surface defects. The brown disc can be used to make minor adjustments to occlusal surfaces.
- The blue high-shine polishing disc can be used on difficult-to-reach areas to achieve a natural high shine finish.

8. Precautions

- The device is to be used on the instruction of and by a dentist or licensed practitioner.
- Always wear gloves when handling instruments.

- c) Eye protection must be worn to shield against ejected particles.
- d) Do NOT use the burs if package is open or damaged. Clean and sterilize them before use.
- e) Surgical mask must be worn to avoid inhalation of any aerosol or dust generated.
- f) Ensure that the bur is securely gripped in the handpiece collet.
- g) Do NOT use worn-out burs.
- h) Handpieces should be sufficiently lubricated and maintained in good working order.
- i) Do NOT exceed the maximum speed of 20,000 rpm for polishing cups.
- j) Do NOT exceed the maximum speed of 25,000 rpm for adjusters.
- k) Do NOT apply excessive pressure on the bur.
- l) Avoid removing the bur at an excessive angle, to avoid leverage and breakage.
- m) Move the bur continuously when in use to avoid localized heating and/or damage to the bur.







9. NOTE


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

Recommended speed for adjusters is 8,000–12,000 RPM. Recommended speed for polishers is 7,000–10,000 RPM. Expected life of adjusters and polishers is 10-15 uses (subject to substrate and applied pressure).

Note: Excessive pressure will lead to overheating and premature degradation of the instruments, as well as possible damage to the pulp tissue.

10. Symbols Glossary

Symbol	Reference No. 21 CFR Part 801, Section	Title - Symbol Description
	Sect. 801.109(b)(1)	By Prescription Only – Caution: Federal law restricts this device to sale by or on the order of a dentist or physician.
Symbol	Reference No. EN ISO 15233-1, Section	Title - Symbol Description
	5.1.1	Manufacturer – Indicates the medical device manufacturer.
	5.1.5	Lot Number – Indicates the manufacturer’s batch code so that the lot can be identified.
	5.1.6	Catalogue Number – Indicates the manufacturer’s catalogue number so that the medical device can be identified.
	5.4.3	Consult Instructions For Use – Indicates the need for the user to consult the instructions for use.
	5.2.7	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process.

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