BruxZir™ Dual Cure Resin Cement

Direction for Use IMPORTANT: PLEASE READ

Description and intended use:

BruxZir™ Dual Cure Resin Cement is a dual cure resin intended to be used for the permanent cementation of ceramic restorations, Zirconia, Lithium Disilicate and CAD/ CAM type materials, veneers, crown and bridge, inlays/onlays, PFM, post/fiber posts.

This cement is made from a complementary hydrophilic resin and filler system, which creates compatibility between the tooth surface and restorative materials. BruxZir Dual Cure Resin Cement is a two-part auto mixing system, which will light cure in under 20 seconds and anaerobically set without light in 90 seconds. Light curing is recommended wherever possible. BruxZir Dual Cure Resin Cement is currently provided in a Translucent White, it is recommended that enamel surfaces, which are uncut enamel, be etched and micro-abraded to optimize bonding of this product to the dental surface. The surface of the restoration should also be pre-etched or abraded to optimize bonding to the restoration. Silane and bonding agents can be used when needed. Silane and bonding agents are not required.

Direction for Use:

Important: Tooth surfaces should be clean, moist and free of any contaminates. The tooth surface (uncut enamel) is to be acid etched. Bonding agents are not required.

Preparation:

- 1. Remove the provisional and temporary cement residue.
- Trial fit the restoration and make any necessary adjustment to contacts and occlusion. We recommend using the BruxZir™ Adjustment & Polishing Kit.
- Clean internal surface of the restoration using one of the following methods:
 - Ceramic restoration: the internal bonding surface should be micro etched with a hydrofluoric acid etchant.
 - Composite restoration: the internal surface should be roughened by sandblasting or air abrasion
 - Metal restoration: the internal surface should be roughened or treated with metal primer as required.
 - d. Zirconia Restoration: the internal surface should be roughened by sandblasting with 50 micron aluminum oxide for BruxZir Full-Strength or 30 micron Cojet sand for BruxZir Esthetic 2 bar /30 Psi for 15 seconds, apply zirconia cleaner such as Ivoclean® (Ivoclar Vivadent), apply 5% NaCIO (Sodium Hypochlorite) to the internal surface for 20 seconds. *DO NOT clean with phosphoric acid*
- 4. Clean tooth, rinse thoroughly and lightly air dry.

Mixing and applying:

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- 1. Remove the sealing cap from the auto mix cartridge. Check the cartridge opening for blockage; remove any paste plugs.
- Bleed the cartridge before installation of the Automix tip. Make sure material emerges uniformly from both opening.

- Insert the Automix tip in the body of the cartridge. Lock in place by turning clockwise. Again, dispense small amount to ensure uniform and even material flow.
- 4. Dispense the material with uniform pressure.
- 5. Re-cap immediately after use.

Inserting the restoration:

- Place matrix bands between teeth to prevent bonding of excess cement to these teeth.
- Bonding agents may be used at this point but not required, if used, a very thin application should occur, and that the bonding agent not extend to any exposed margin. DO NOT cure the bonding agent at this point.
- Apply cement directly onto the internal surface of the restoration.
 - a. Gently seat the restoration onto the tooth.
 - b. Press down firmly
 - Clear the contacts with dental floss before curing is allowed and remove excess cement.

Working time / light cure:

- Light cure the margins for 20 seconds for each tooth surface.
 NOTE: Curing may require greater time for larger restorations or those, which are quite thick. Self-curing will proceed upon seating.
- 2. Avoid direct exposure of the cement to intense light.
- 3. Self-cure, starts when seated initial set in 90 seconds.
- 4. Complete set in 4 minutes

Finish and Polish:

- 1. Ensure all excess cement is removed.
- Adjust occlusion and polish if needed. Recommend using the diamond burs, polishing cups and polishing discs from the BruxZir™ Adjustment & Polishing Kit.

Precautions:

- 1. For professional use by dental personnel only.
- 2. Wear protective eyewear and gloves.
- Do not leave any cement residues in the mouth or gingival sulcus.
- 4. BruxZir Dual Cure Resin Cement may cause irritation to eyes and skin on contact. Take all necessary precautions to avoid contact with eyes and soft tissue. If material contacts eyes, rinse with water. If materials contact skin, wash skin with soap and water. Seek medical attention if irritation persists.

Storage and Stability:

- Store BruxZir Dual Cure Resin Cement tightly capped in original container, in a refrigerator.
- 2. Avoid direct sunlight and extremes of temperature.
- 3. Shelf life of unopened product; 18 months from date of manufacture, when properly stored.
- Re-cap immediately after use.
 Designed to be used at room temperature between 65-70°F.

Symbols Glossary

Symbol	Reference No. 21 CFR Part 801, Section	Title - Symbol Description
R _{Only}	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.
***	5.1.1	Manufacturer – Indicates the medical device manufacturer.
LOT	5.1.5	Lot Number – Indicates the manufacturer's batch code so that the lot can be identified.
REF	5.1.6	Catalogue Number – Indicates the manufacturer's catalogue numbers o that the medical device can be identified.
Ţ <u>i</u>	5.4.3	Consult Instructions For Use – Indicates the need for the user to consult the instructions for use.
NON STERNLE	5.2.7	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process.
	5.1.3	Date of manufacture- Indicates the date when the medical device was manufactured.
	5.1.4	Use-by date- Indicates the date after which the medical device is not to be used
**	5.3.2	Keep away from sunlight-Indicates a medical device that needs protection from light sources.



MANUFACTURED For:
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