

Light Cure Veneer Cement

(Instructions for Use)

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U.S. Federal Law restricts this device to sale by or on the order of a dental professional. Prior to use the product, please read the instruction carefully.

GENERAL DESCRIPTION

Light Cure Veneer Cement is a light curing, esthetic cementation system that is designed for use with porcelain/ceramic and composite veneer restorations. The simple and versatile shade selections allow this material to be used with a wide range of veneer cases. The system contains following seven shade options: TR (Translucent), A0 (Light+), A1 (Light), A2 (Medium), A3 (Dark), White (White Opaque), Opaque (Universal Opaque) to cover a variety of applications. The Veneer Cement kit includes a Light Cure Self-etch Dental Adhesive with the option of the tooth surface being total etch, enamel etch and self-etch techniques; and a Ceramic Priming Agent for the ceramic and/or porcelain surface priming; as well as a Phosphoric Acid Etching Gel for your application technique of choice. The principal organic components are mixtures of dental methacrylate resins (TEGDMA, EBPADMA and UDMA). The inorganic filler loading is about 40% by volume having particle size range of about 0.01 to 3 microns.

Light Cure Veneer Cement is radiopaque, allowing for easy identification on radiographs.

- Packaging specifications: 0.25g, 1g, 2g, 3g, 3.5g, 4g, 4.5g, 5g, 5.5g, 6g, 6.5g, 7g, 7.5g, 8g, 8.5g, 9g, 9.5g, 10g, 11g, 12g
- Shade: TR (Translucent), A0 (Light+), A1 (Light), A2 (Medium), A3 (Dark), White (White Opaque), Opaque (Universal Opaque)
- Accessories: Dispensing Tip (20G black needle)

INDICATIONS

Light Cure Veneer Cement is used for permanent cementation of veneer made from materials of porcelain/ceramic and composites.

CONTRAINDICATIONS

- Not to be used for patient known to be allergic to methacrylate resins.
- Not for exposed pulp or pulpitis needing treatment.

SIDE EFFECTS

- This product or one of its components may cause hypersensitive reactions.

OPERATING PROCEDURES

1. Prepare the tooth according to the principles of adhesive dentistry. Make sure to clean and remove surface debris thoroughly from the preparation site.

2. Apply a small amount of HuGe Veneer Try-in Gel to the restoration. Seat it on the tooth surface with light pressure. Assess shade and remove the restoration. Once the desired shade has been selected, remove the veneer and rinse thoroughly with water. Remove any organic debris by cleaning with alcohol or acetone, followed by cleaning in water in an ultrasonic cleaner. Clean the tooth thoroughly with both water and pumice.

- Note: Try-in Gels have unlimited working times and will not set.

3. Ensure all restorations are properly treated and etched according to the manufacturer's instruction.

4. Apply 1-2 coats of Ceramic Priming Agent to the restoration(s) and allow the Primer to stand for 60 seconds. Air dry.

5. Apply 37% Phosphoric Acid Etching Gel to the tooth surface for 15 seconds and water rinse the surface thoroughly for 10 seconds. It is important not to splash the etch into eyes, onto soft tissues or skin.

6. Dry with clean, oil-free, air without desiccating the dentin. Do not allow etched surface to become contaminated with saliva or blood during the bonding procedure.

- Note: Never use excessive force on syringe plunger to dispense etch which may lead to over dispensing of the material. If resistance is felt, replace current tip with a new tip and check flow extra-orally.

7. Apply two consecutive coats of Light Cure Dental Adhesive to tooth within 10 seconds to ensure a shiny surface.

8. Air dry for 10 seconds using a gentle stream of air to remove solvent. Hold the air syringe about 2 cm from preparation or restoration; avoid disturbing the resin surface. If surface shine disappears after drying, re-apply with the Light Cure

Dental Adhesive and re-dry.

9. Place the selected shade of Light Cure Veneer Cement onto the primed veneer. Carefully place veneer. Allow excess cement to exude.

· Note: The Light Cure Veneer Cement shades can be mixed for customization to further “warm” or “brighten” the shade. If shades are mixed, be careful not to incorporate air into the mixture.

10. Light cure for 1-2 seconds to tack the veneers into place. Remove excess cement as needed.

11. Light cure each surface of the restoration for 20 seconds.

12. Finish with diamond/carbide burs, if necessary.

NOTE

- Refer to outer package for expiration date. Do not use after expiration date.
- For dental use only. Do not use for indications or applications that are not specifically noted in the instructions for use.
- Follow the Operating Procedures when using.
- Notification of any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in your country.

PRECAUTIONS

- Uncured methacrylate resin may cause contact dermatitis and damage the pulp. Avoid contact with skin, eyes and soft tissue. Wash thoroughly with water after contact.
- Dispose in accordance with local regulations.
- Dispensing Tips and micro-applicators are for single use only, to prevent cross-contaminations between patients.
- Keep material out of children’s reach.
- This product is easy to polymerization early if exposed to natural light or artificial light. Do not place under strong light during use.
- Recommend to store in a refrigerator when not in use for better life.
- If one of the following is noted, it is a sign that the material is losing its intended efficacy and should no longer be used:
 - Nothing comes out of the syringe although there is material left inside.
 - Solid or gel-like coagulation is detected in the pastes when dispensed.

STORAGE

- Store the cement material at 2-25°C and away from direct light. Use the material at normal room temperature.
- Shelf life: 3 years from date of manufacture










WARRANTY

Rizhao HuGe Biomaterials Company, Ltd. warrants this product is free from defects in material and manufacture. HUGE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user’s application. If this product is defective within the warranty period, your exclusive remedy and HUGE’s sole obligation shall be repair or replacement of the HUGE product.

LIMITATION OF LIABILITY

Except where prohibited by law, HUGE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

SYMBOLS FOR USE IN THE LABELING

-  - Use-by date  - Caution  - Batch code  - Temperature limit  - Country of manufacture
-  - Consult instructions for use  - Keep dry  - Keep away from sunlight  - Unique device identifier
-  - Authorized representative in the European Community  - Medical device  - Manufacturer

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