

## Dual Cure Resin Cement

### (Instructions for Use)

Version: 01

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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

Dual Cure Resin Cement is a versatile and ultimate dental dual cure (chemical and/or light cure) luting cement containing paste-paste of Base and Catalyst. The mixing ratio, based on volume, is 1 part base paste : 1 part catalyst paste.

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.

Dual Cure Resin Cement is delivered in either two separated single syringes for Hand-mix or double-barrel syringes for Automix and comes in seven shades: TR (Translucent), A0 (Light+), A1 (Light), A2 (Medium), A3 (Dark), White (White Opaque) and Opaque (Universal Opaque).

Dual Cure Resin Cement is radiopaque, allowing for easy identification on radiographs.

A Light Cure Dental Adhesive with the option of the tooth surface being total etch, enamel etch or strictly self-etch techniques; and a Ceramic Coupling Agent for the ceramic and/or porcelain surface priming; as well as a 37% Phosphoric Acid Etching Gel for your application technique of choice.

#### WORKING TIME

In self-curing mode, the working and setting times depend on the ambient temperature. Once Dual Cure Resin Cement has been dispensed from the automix syringe or hand-mixed, the following times apply:

	Times and conditions
Working time	≥ 60 s at room temperature (23°C)
Setting time (including working time)	≤ 4.5 minutes intraorally (37°C)

#### INDICATIONS

Dual Cure Resin Cement is a dental luting system designed for cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers, dental posts and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.

#### CONTRAINDICATIONS

- Patient known to be allergic to methacrylate resins should be avoided to use this product.
- Not for exposed pulp or pulpitis needing treatment.

#### SIDE EFFECTS

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

#### OPERATING PROCEDURES

##### · Cementation of all ceramic/porcelain restorations

1. Applying dental adhesive to tooth surface following the Directions For Use;
2. Applying Ceramic Coupling Agent to the internal surface of the ceramic restoration and leave for 60 seconds before drying with compressive air;
3. Placing the 1:1 mixed cement onto the primed surface and seat on the tooth in position. In general, the set time for the dual cure cement is about 4.5 minute (start from the mixing and under oral temperature); if the restoration is translucent enough, one can light cure the cement through the restoration surface for 20 seconds (for light output is < 1000 mw/cm<sup>2</sup>) or 10 seconds (for light output is >1000 mw/cm<sup>2</sup>) for instant cure.

##### · Cementation of posts made from fiber composites or ceramics, or metals

1. After trial, adjusting the occlusal as needed. Then applying the adhesive to tooth surfaces per the product directions for use to pre-treat the tooth. (The ceramic priming agent should be applied to the ceramic post surface for 60 seconds before drying.)
2. Filling enough amount of the 1:1 mixed resin cement into the canal using helical mixer, applying additional cement

to the post and seat the post into the canal. The cement will set in about 4.5 minutes.

#### · **Cementation of metal restorations**

1. Apply the adhesive to tooth surface per the directions for use.
2. On the restoration internal surface, apply a coat of layer of the adhesive and air dry.
3. Place the mixed cement inside the restoration. The resin cement will have a minimum working time of 60 seconds and a maximum setting time of about 4.5 minutes (intraorally) from the start of mixing.
4. Seat restoration and apply even pressure with a bite stick, allowing access cement to vent.
5. For easy and clean removal of the cement access, one can light cure the access for 1 second and then remove it with an explorer.

#### **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.
- Helical mixer are for single use only, to prevent cross-contaminations between patients.
- Keep material out of children's reach.
- Recommend to store in a refrigerator when not in use for better life.
- If a dry working field cannot be established or the stipulated working technique cannot be applied.

#### **STORAGE**

- Store Dual Cure Resin Cement at 2-25°C, away from direct light with the cap closed tightly. Use the material at normal room temperature.
- Shelf life: 2 years from date of manufacture

#### **WARRANTY**

Rizhao HuGe Biomaterials Co., 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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