Dual Cure Resin 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

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)

Physical Properties

Compressive Strength (MPa)	≥ 200
Flexural strength (MPa)	≥ 50
Water sorption (μg/mm³)	≤ 40
Solubility (μg/mm³)	≤ 7.5

Indications

- Permanent cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.
- Permanent cementation for all types of root canal posts.
- Core build-ups.

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

1.Cementation of all ceramic/porcelain restorations

①Applying dental adhesive to tooth surface following the Directions For Use.

②Applying Ceramic Coupling Agent to the internal surface of the ceramic restoration and leave for 60 seconds before drying with compressive air.

③Remove the syringe plug or used mixing tip. Extrude a small amount of material directly out of the syringe onto a paper towel/tissue, until it is evident that equal amounts of base and catalyst are being extruded. This will ensure that optimal mixing is achieved.

④Attach the helical mixer and twist clockwise (90 degrees) to lock in place.

⑤Placing 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 minutes (start from the mixing and under oral temperature); if the restoration is translucent enough, one can light cure the cement (exposure to a halogen or LED light in the 400-500nm range) through the restoration surface for 20 seconds (for light output is < 1000 mw/cm²) or 10 seconds (for light output is >1000 mw/cm²) for instant cure.

2.Cementation of metal restorations

①Apply the adhesive to tooth surface per the directions for use.

②On the restoration internal surface, apply a coat of layer of the adhesive and air dry 10s with gentle stream of air.

③Follow the steps of ③-④ above in section 1.

④Place 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.

⑤Seat restoration and apply even pressure with a bite stick, allowing excess cement to vent.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.

3.Cementation of posts made from fiber composites or ceramics, or metals.

①Applying dental adhesive into the prepared post space preparation of the root canal and onto the contact surfaces (preparation/cavity) using a brush according to the manufacturer's instructions for use.

②Remove excess adhesive from the root canal using paper points.

③Dry adhesive bond layer using a gentle stream of air for 10s.

④Proceed as described in section 1 step ③-④.
⑤Dispense resin cement directly from the syringe into the prepared root canal using the helical mixer with root canal tip.
Note: It is not recommended to use a lentulo spiral to introduce resin cement material into the root canal.
⑥Coat the root canal post completely with the mixed resin cement material. Insert the post into the root canal using gentle pressure. Remove excess resin cement material using the appropriate instrumentation. After each use, do not remove the helical mixer.
⑦Prepare the core build up as soon as the resin cement material has completely cured. The resin cement material can be light-cured for 20s to accelerate polymerization or to reduce the inhibition layer.

4.Core Build-Ups
①Applying dental adhesive onto the contact surfaces (preparation/cavity) using a brush according to the manufacturer's instructions for use.
②Dry adhesive bond layer using a gentle stream of air for 10s.
③Proceed as described in section 1 step ③-④.
④If necessary, place a matrix band around the prepared tooth.
⑤Apply resin cement directly to the preparation. After each use, do not remove the helical mixer.
Note: it is important that there be enough healthy tooth structure remaining (1.5 mm apical around the tooth stump) so that the appropriate ferrule effect can be created.
⑥The compound can be polymerized with light in order to speed up the hardening process or minimise the inhibition layer.

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 mixers 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.

Storage
- Store Dual Cure Resin Cement at 2-25℃, 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
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
LOT — Batch code
 — Temperature limit
 — Keep away from sunlight
 — Keep dry
 — Consult instructions for use
 — Manufacturer
 — Country of manufacture
MD —Medical device
UDI —Unique device identifier
EC REP — Authorized representative in the European Community
Rx ONLY — Caution:U.S.Federal Law restricts this device to sale by or on the order of a dentist or professionals.

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