HUGE

Resin Modified Glass Ionomer Cement-Luting

(Instructions for Use)

Version: 01
Date of Issue: Sept. 15, 2021

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

Resin Modified Glass Ionomer Cement (RMGI) Luting possesses unique triple curing mechanisms of conventional acid-base glass ionomer reaction, methacrylate resin chemical curing and light curable on demand. It is radiopaque (equivalent of >2.0 mm of aluminum) to better observe the condition of the abutment teeth in the prosthesis, as two-part paste/paste RMGI luting cement material. RMGI Luting provides the common benefits typical of other glass ionomer materials, along with the dual cure two-part paste of greater convenience over the traditional powder/liquid luting systems. The filler content of this system is primarily a combination of traditional silane treated barium-boro-silicate glass filler and acid reactive fluoroaluminosilicate glass filler having a hybrid particle size range from about 0.01 up to about 3 micrometers. The combined inorganic filler loading is about 65% by weight, while the resin system has a combination of phosphate and other methacrylate resins which are not having any Bisphenol A , or BPA derivative resin and/or Bis-GMA resin.

This cement achieves sufficient bond strength to tooth structure without the need of an etchant or an adhesive. Excess cement can be easily removed by allowing the cement to reach its gel state either through self-curing or tack-curing.

CLASSIFICATION

type 2 class 3 group 1

INDICATIONS

Cementation of:

· Cementation of porcelain-fused-to-metal (PFM) crowns and bridges

· Cementation of metal crowns, inlays and onlays

· All-zirconia strengthened core ceramic restorations

· Cementation of resin inlays, onlays, crowns and bridges

· Final cementation of PFMs, metal crowns or all-zirconia strengthened core ceramic restorations to implant abutments

CONTRAINDICATIONS

· Pulp capping.

· Sensitivity, in rare cases in patients with extreme sensitivity.

PRECAUTIONS

· Hold the restoration with moderate pressure while cleaning excess cement.

· Do not use provisional cements containing eugenol, as these materials may interfere with the curing of the RMGI Luting Cement.

· Use the product within 12 months of opening the pouch. Always ensure that it is not past the expiration date printed on the syringe label.

· 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.

· 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.

· Carry out daily maintenance as prescribed by dentist.

· For professional use only.

· Cover the cap immediately after use to prevent foreign matter from entering the product and polluting the product.

SIDE EFFECTS

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

OPERATING PROCEDURES

1. Prepare the tooth: remove the provisional restoration. Clean the preparation with pumice and water. Rinse thoroughly with water after cleaning preparation.

2. Using non-contaminated air to dry the preparation so that the surface has a somewhat glossy appearance. Do not over dry or desiccate the preparation.

3. Try in the restoration to ensure proper fit and occlusion. Adjust if needed.Thoroughly clean the bonding surfaces of the restoration.

4. Remove the cap from the syringe.If the level of material is not even, bleed excess material from the syringe until the base and catalyst both flow evenly.Then attach the helical mixer to the syringe (for auto-mixing).

5. Dispensing of the material can be done as follows:

a. Inlay/Onlay – Dispense the cement directly into the cavity preparation covering all surfaces. Seat the restoration onto the tooth preparation, allowing the cement to flow from all

sides.
b. Crown – Dispense the cement directly onto the restoration, covering all surfaces. Seat the restoration onto the tooth preparation, allowing the cement to flow from all margins.
6. Once the restoration is seated, remove the excess cement. Excess cement is best removed in its gel state with a scaler. Gel state can be achieved by tack-curing excess with a light for approximately 2 seconds, or by allowing the cement to self-cure until it feels rubbery.
7. Material should completely set within 4 minutes and 30 seconds after placement in the mouth.
8. Finish the restoration and check occlusion when material has completely set.
9. Remove the used helical mixer and replace it with the original cap; do not leave the used helical mixer on the syringe.

IMPORTANT NOTE

· Verify that the laboratory has pre-treated the final restoration in accordance with manufacturer's instructions. Helical mixer are for single patient use only, to prevent cross-contamination between patients.

· The mixing is done by using auto-mix, the mixing time is shortened due to the instant glass ionomer reaction from the thorough mixing action under pressure, which cause the mixture thickened up shortly after the auto-mix. Therefore, it is required to dispense a sufficient amount of the mix all at once and delivered it to a cavity or on a pad initially to avoid having difficulties to extrude further after the mixed material stayed in the auto-mixing element for more than one minute.

WORKING CHARACTERISTICS

· Mode of Cure: Dual Cure (ISO 9917-2: Class 3 Resin Modified Cements)
· Method of Mixing: Auto-Mix
· Film thickness(maximum): 25μm
· Mixing Ratio (base:catalyst): 1:1
· Mixing Time Auto-Mix
· Working Time (minimum)* 1 minute 30 seconds
· Intra-oral Setting Time (maximum, from initial mix)* 4 minutes 30 seconds
* These times may vary based on storage conditions, temperature, humidity, and age of product.

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.

STORAGE

· Store RMGI Luting 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

Rizhao HuGe Biomaterials Co., Ltd. (HuGe) 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 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

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