

Shandong Huge Dental Material Corporation
 No. 68 Shanhai Road, Donggang District, Rizhao
 City, Shandong Province, 276800, P.R. China
 www.hugedental.com marketing@hugedental.com

MedNet EC-REP GmbH
 Borkstrasse 10, 48163 Muenster, Germany

CE ISO 13485:2016
 FDA cleared for marketing
 1639

Glass Ionomer Cement-Luting II Instructions for Use

For use only by a dental professional in the recommended indications.

RECOMMENDED INDICATIONS

1. Cementation of metal-based inlays, onlays, crowns and bridges.
2. Cementation of high strength (zirconia based) all ceramic crowns and bridges.
3. Cementation of posts and screws made of metal or high-strength ceramic.
4. Cementation of orthodontic bands.
5. Restoration of caries in unstressed area.

Items	For luting	For filling
Powder/liquid ratio (g/g)	1.6~1.8/1.0	2.3 ~2.5/1.0
Mixing time (min., sec.)	45"	45"
Working time (min., sec.) (at 23°C) (from start of mixing)	2'00"~3'00"	1'30"~2'00"
Net setting time	1'30"~8'00"	1'30"~6'00"

CONTRAINDICATIONS

1. Pulp capping.
2. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

1

DIRECTIONS FOR USE

FOR LUTING

1. TOOTH PREPARATION

- a) Prepare tooth in usual manner. For pulp capping, use calcium hydroxide.
- b) Clean the prepared teeth with pumice and water.
- c) Blow the preparation dry in only 2-3 short intervals with water and oil-free air or dab dry with cotton pellets. Do not over-dry!

2. RESTORATION PREPARATION

Make sure that the restoration is pretreated and handled according to the manufacturer's instructions.

3. POWDER AND LIQUID DISPENSING

- a) The standard powder to liquid ratio is 1.6g~1.8g/1.0g (slightly adjusted according to use habit and environmental temperature), 1 level scoop of powder to 2 drops of liquid.
- b) For accurate dispensing of powder, lightly tap the bottle against the hand. Do not shake or invert.
- c) Hold the liquid bottle vertically and squeeze gently.
- d) Close bottles immediately after use.

4. MIXING

Dispense powder and liquid onto the pad. Using the plastic spatula, add all the powder to the liquid. Mix rapidly within 45 seconds.

Note:

When mixing larger amounts, divide the powder into two equal parts.

Mix the first portion with all of liquid fully. Incorporate the remaining portion and mix the whole thoroughly (total about 45 seconds).

2

5. CEMENTATION

- a) Coat the internal surface of the restoration with sufficient cement and seat immediately. The working time is 2~3 minutes from start of mixing at 23°C (73.4°F). Higher temperature shortens working time.
- b) Maintain moderate pressure.
- c) Start removing excess cement when the excess cement feels rubbery.
- d) Finishing can be started 1.5~8 minutes after seating the restoration.
- e) During application, water and saliva must be prevented from entering the working area.

FOR FILLING

1. POWDER AND LIQUID DISPENSING

- a) The standard powder to liquid ratio is 2.3g ~ 2.5g: 1.0g (slightly adjusted according to use habit and environmental temperature), 1 level scoop of powder to 1 drop of liquid.
- b) For accurate dispensing of powder, lightly tap the bottle against the hand. Do not shake or invert.
- c) Hold the liquid bottle vertically and squeeze gently.
- d) Close bottles immediately after use.

2. MIXING

Dispense powder and liquid onto the pad. Using the plastic spatula, divide the powder into 2 equal parts. Mix the first portion with all of the liquid. Incorporate the remaining portion and mix the whole thoroughly (total time within 60 seconds);

3

3. RESTORATIVE TECHNIQUE

- a) Prepare tooth using standard techniques. Only remove the carious substance; no extensive mechanical retention required.
- b) Blow the cavity dry in only 2-3 short intervals with water and oil-free air or dab dry with cotton pellets. Do not over-dry!
- c) Mix the required amount of cement. Working time is 1.5~2 minutes at 23°C (73.4°F). Higher temperatures will shorten working time.
- d) Remove surface moisture, but DO NOT DESICCATE.
- e) Transfer cement to the preparation using a syringe or suitable placement instrument.
- f) Form the contour during the first 2 minutes of setting.
- g) Setting time is 1.5~6 minutes from start of mixing depending on powder to liquid ratio (23°C).

4. FINISHING

- a) One visit treatment
 - 1) 7-10 minutes after initial set, correct the contour, finish and polish WITHOUT WATER SPRAY using standard techniques.
 - 2) Apply standard GIC water-proofing agent or Vaseline on surface of restoration to proof water.
- b) Standard method
 24 hours after placement, finish and polish the restoration under water spray using standard techniques.

SHADE

0, A1, A2, A3

4

STORAGE

Store in a cool and dark place (4-25°C) (39.2-77.0°F).
 (Shelf life: 2 years from date of manufacture)

PACKAGES

1. powder,
2. liquid,
3. powder measure,
4. mixing pads

CAUTION

1. In case of contact with oral tissue or skin, remove immediately with a sponge or cotton soaked in alcohol. Flush with water. To avoid contact, a rubber dam and/or cocoa butter can be used to isolate the operation field from the skin or oral tissue.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. DO NOT mix powder or liquid with components of other glass ionomer cements.
4. 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.

Warranty

HUGE warrants this product will be 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 product 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.

5

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

- Temperature limit
- Keep away from sunlight
- Keep dry
- Caution
- Use-by date
- Batch code
- Manufacturer
- Recycling

- Authorized representative in the European Community

- Consult instructions for use

- Caution: U.S. Federal Law restricts this device to sale by or on the order of a dentist or professionals.

- Country of manufacture

- Medical device

- Unique device identifier

6