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 1639 FDA cleared for marketing

Glass Ionomer Cement-Luting I 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.

Powder/liquid ratio (g/g)	1.6~1.8/1.0
Mixing time (min., sec.)	45"
Working time (min., sec.) (at 23°C) (from start of mixing)	≤ 3'00"
Net setting time (from end of mixing)	1'30"~8'00"

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.

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DIRECTIONS FOR USE

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.

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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).

5. CEMENTATION

- a) Coat the internal surface of the restoration with sufficient cement and seat immediately. The working time is less than 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.

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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 pad

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. This product is not indicated for filling or core build-up.

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5. 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.

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 labelling

- Temperature limit - Keep away from sunlight

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- Keep dry



- Use-by date



- Batch code



- Recycling



- Manufacturer



- Caution



- 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

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