





Light Cured Glass Ionomer Restorative Cement (Powder / Liquid)

ISO 9917-2:2017

DIRECTIONS FOR USE

FEATURES:

Self-adhesive cement. Suitable for ART, minimally invasive procedures and glass ionomer/composite "sandwich" restorations. Has good flexural strength. Mixes easily. Radiopaque. Contains fluoride.

INTENDED PURPOSE:

Restoration of lost tooth structure

INTENDED PATIENT POPULATION: From child to geriatrics

INTENDED USER:

This product has been formulated for use in dentistry and is intended for use by dental professionals only.

CLINICAL BENEFIT:

To restore the function of the teeth and help maintain the integrity of the remaining tooth structure.

INDICATIONS FOR USE:

- Deciduous cavity restoration.
- Class III and V restorations.
- Core Build up.

CONTRA-INDICATIONS:

Pulp capping - use calcium hydroxide to line cavities where remaining dentin may be thin. Do not use eugenol-containing materials.

CONTENTS OF PACK:

Powder 15g, liquid 6ml, measuring scoop, instructions for use

PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material.
- Avoid contact of liquid and powder with oral mucosa, eyes, and skin.
- In case of contact, wash thoroughly with water and obtain medical advice
- DO NOT use product for any purpose other than indicated.
- Do not mix powder or liquid with other glass ionomer components.

PROCEDURE

- (1) PREPARATION:
- Prepare cavity and clean with polyacrylic acid toothcleanser in normal way.
- Line deep cavities with calcium hydroxide if appropriate.

(2) MIXING:

Place 1 level scoop of powder and 1 bubble-free drops of liquid on pad and mix thoroughly with flat bladed spatula to creamy consistency.

DO NOT ADD POWDER IN SMALL INCREMENTS.

Total mixing time: 30 seconds. Working time: 1 minute 30 seconds from start of mix at 23°C. Setting time: 6 minutes from placement in the oral cavity.

For test purposes, the ratio of powder 0.90g to liquid 0.20g tested at 23±1°C & RH 50±10%.

ISO 9917-1 net setting time: 2 to 6 minutes from start of mix at 36-38°C & RH 90-100%.

(3) PLACEMENT:

- Pack cement in to cavity and light cure the entire surface.
- A3 shade will light cure to ~3mm depth in 20 seconds.

(4) CURING

- After placing and contouring the restoration, cure with a light unit.
- Select the light curing time in the table below.
- Light cure the entire surface of the restoration.
- For deep cavities, the layering technique is recommended, Place in a layer of up to 2mm depth and cure with a dental light cure unit.

| Light Curing Unit | LED curing unit | Halogen lamp curing unit |
|-------------------|---------------------------|--------------------------|
| Light Curing Time | 10 seconds | 20 seconds |
| Wavelength | 440-490 nm | 400-500 nm |
| Light Intensity | ≥ 1000 mW/cm ² | ≥ 500 mW/cm ² |

- Use a dental light-curing unit having specifications equivalent to those described above.
- When using a unit having performance other than these recommendations, follow the instructions for that unit

(5) FINISHING:

- After light curing or at 7 minutes after placement, the material is hard enough to finish but petroleum jelly must be used as a lubricant to prevent excess heat generation.
- White stones and alumina discs are recommended for optimum results.
- Final finishing is best carried out at a subsequent visit.

STORAGE



Store in a cool, dry place (5-25°C).

Always replace cap immediately after use.

EXPIRY:

 \Box The expiry date is shown in year, month format. Do not use the product after this date.

DISPOSAL:

Dispose of the contents and containers in accordance with relevant local and national requirements.

POSSIBLE SIDE EFFECTS / RESIDUAL RISKS:

- •This product contains substances that may cause and allergic reaction.
- · Restorations have the potential to fracture depending on patient habits.
- Restorations have the potential to fall out depending on patient habits.

BATCH CODE:

atch code gives an open date of manufacture in month, year, day format LOT numerical suffix to uniquely identify the batch of material. Please quote this batch number in all correspondence.

DEVICE CODES: 300

| REF | AH0300 |
|-----|--------|
| | AH0301 |
| | AH0302 |
| | AH0303 |

15g Powder A2 / 6ml Liquid 15g Powder A3 / 6ml Liquid 15g Powder A3.5 / 6ml Liquid 15g Powder B2 / 6ml Liquid

COMPOSITION:

| Composition | % by weight |
|---------------------|-------------|
| Glass | 70 – 100 |
| Deionised Water | 5 – 10 |
| PAA | 1 – 10 |
| Methacrylate resins | 5 – 10 |
| HEMA | 5 – 10 |
| Stabiliser | <1 |
| Activators | 0-5 |

AHL operate a policy of continuing surveillance & monitoring of our products. If you experience any incidents relating to the use of this product, please immediately contact us at the below address stating the batch number shown on the packaging. If you experience any serious incident relating to the use of this product, please immediately contact AHL at the below address and the competent authority of the territory you are in.

A summary of safety & clinical performance (SSCP) is available via the EUDAMED database. https://ec.europa.eu/tools/eudamed

Caution: U.S. Federal Law restricts this device to sale by or on the order of a dental professional.

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