



AHL Generic



GLASS IONOMER AESTHETIC RESTORATIVE (WATER MIX)

ISO 9917-1:2007 Glass Polyalkenoate Class 4.2.c

DIRECTIONS FOR USE

FEATURES:

Glass Ionomer restorative cement powder is a fast setting glass polyalkenoate material activated by mixing with water. The mixed cement adheres directly to enamel, dentine and cementum. This material is available in 7 translucent shades and 2 speeds. For optimum results the shade guide MUST be used. 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:

- Class V cavities (particularly erosion lesions).
- Class III cavities.
- Class I and II cavities in deciduous teeth.
- Pits and fissures.

CONTRA-INDICATIONS:

- Pulp capping.

CONTENTS OF PACK:

Powder 10g, dispensing bottle, dropper tip, 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.

PROCEDURE

(1) CAVITY PREPARATION:

Glass Ionomer restoratives, because of their adhesive qualities, can be used with minimal cavity preparation techniques. (Adhesion to set amalgam restorations may be useful in certain situations.) Cavity liner is required only in the deepest cavities where calcium hydroxide should be used. In class V erosion lesions, Tooth Cleanser (25% polyacrylic acid solution) should be applied on a pledget of cotton wool for 30 seconds to clean the tooth surface. Wash with water and dry using oil-free air. In areas which are heavily coated with plaque or tartar, prophylaxis using oil-free prophylaxis paste prior to tooth cleansing is required. In cut cavities, the use of tooth cleanser is not required unless subsequent contamination with saliva occurs.

(2) MIXING:

(Powder : Liquid ratio 7:1 m:m). Invert bottle to fluff powder; this ensures correct scoop weight. Do not compress powder against side of the bottle with the scoop. Remove excess powder using a flat spatula blade, again taking care to avoid compressing the powder. To deliver accurate water drops, hold bottle vertically. If water does not drop from the TIP of the steel tube, clean this with a tissue. Use a glass block for best results and a stainless steel spatula. Place 2 scoops of powder and 2 drops of water onto the glass block or mixing pad. Incorporate half the powder into the water as quickly as possible (5-10 seconds) and then add the remainder and spatulate to a THICK putty-like consistency.

DO NOT ADD POWDER IN SMALL INCREMENTS.

Total mixing time: 30 seconds.

Regular Set:

Working time: 1 minute 45 seconds from start of mix at 23°C.

Setting time: 3 minutes 30 seconds from placement in the oral cavity.

Express Set:

Working time: 1 minute 20 seconds from start of mix at 23°C.

Setting time: 3 minutes from placement in the oral cavity.

For test purposes, the ratio of powder 1.05g to liquid 0.15g 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:

Apply to cavity using normal instruments (non-stick aluminium instruments are particularly suitable). To avoid cement adhering to steel instruments, dip the clean instrument either into the powder or methylated spirit. If stainless steel matrices are used, they should be lightly coated with petroleum jelly.

(4) FINISHING:

Best results are obtained by polishing with abrasive discs and stones using water spray lubrication during a subsequent visit. At 5 minutes after placement the material is hard enough to finish using abrasive discs and stones, but petroleum jelly must be used as lubricant to prevent excess heat and desiccation of the cement. After finishing, the surface should be coated with varnish for protection of moisture.

STORAGE:



Store in a cool, dry place (5-25°C).

Always replace cap immediately after use.

EXPIRY:



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 an 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:



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

DEVICE CODES:



012X1R	012X1E	1 Light
012X2R	012X2E	2 Light Yellow
012X3R	012X3E	3 Universal
012X4R	012X4E	4 Light Grey
012X5R	012X5E	5 Brown Yellow
012X7R	012X7E	7 Yellow Grey
012X8R	012X8E	8 Dark Yellow Grey

COMPOSITION:

Composition	% by weight
Glass powder	60 – 80
Water	10 - 25
Polyacrylic Acid	10 – 20
Tartaric Acid	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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