



AHL Generic



GLASS IONOMER LUTING CEMENT (WATER MIX)

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

DIRECTIONS FOR USE

FEATURES:

Adheres chemically to tooth substance and non-precious alloys to optimise retention. Rapidly increasing pH during setting produces excellent biocompatibility. Superb translucency for optimum aesthetics under glass-ceramic jacket crowns. Contains fluoride.

INTENDED PURPOSE:

Attach selected dental prostheses.

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:

- For cementing orthodontic brackets and bands
- For cementing metal and ceramic crowns, bridges, inlays and onlays.

CONTRA-INDICATIONS:

- Pulp capping.

CONTENTS OF PACK:

081X2 – powder 15g, dispensing bottle, dropper tip, measuring scoop, IFU

081X3 – powder 30g, dispensing bottle, dropper tip, measuring scoop, IFU

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) MIXING:

The recommended powder: liquid ratio is 3.6:1 mm at 22-24°C and RH 40-60%. Use a clean and dry polished glass slab and a flat-bladed, stainless steel spatula. Invert bottle to "fluff" powder for accurate dispensing. Measure ONE scoop of powder onto glass slab, taking care not to compress powder against side of bottle with the scoop. Remove excess powder from the scoop using a flat-bladed spatula. Dispense TWO drops of WATER onto slab. To deliver accurate water drops, hold bottle vertically. If water does not drop from the "tip" of steel tube, clean with a tissue. Divide powder into two equal portions and incorporate half the powder into WATER and mix for 10-15 seconds, then add remaining powder and spatulate to a creamy consistency.

DO NOT ADD POWDER IN SMALL INCREMENTS.

Total mixing time: 30 seconds.

Working time: 1 minutes 45 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 1.08g to liquid 0.30g 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%.

(2) PLACEMENT:

Apply the cement on completion of mix. Using normal instruments. Excess cement may be removed immediately or after cement has hardened. DO NOT ATTEMPT TO REMOVE CEMENT WHILST IN RUBBERY PHASE AS ADHESION MAY BE IMPAIRED. Clean instruments immediately on completion.

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.

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:



081X2 15g Powder
081X3 30g Powder

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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