



AHL Generic



GLASS IONOMER LUTING EXTRA (POWDER-LIQUID)

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

DIRECTIONS FOR USE

FEATURES:

Adheres chemically to tooth substance and non-precious alloys, which gives maximum secure retention. 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 metal and ceramic crowns, bridges, inlays, and onlays.
- For cementing orthodontic brackets and bands.

CONTRA-INDICATIONS:

- Pulp capping.

CONTENTS OF PACK:

Powder 35g, Liquid 21ml, 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) MIXING:

The recommended powder: liquid ratio is 2:1 (mm) at 22-24°C and 40-60% R.H. The use of a clean dry, polished glass slab or paper pad and a stainless steel spatula is recommended. Invert bottle to "fluff" powder for accurate dispensing. Measure ONE scoop of powder onto a glass slab or paper pad, taking care not to compress powder against side of bottle with the scoop. Remove excess powder from the scoop using the straight edge of the spatula. Dispense ONE "bubble-free" drop of liquid onto the glass slab or paper pad. Incorporate half the powder into the liquid and mix for 15 seconds, then add the remaining powder and mix to a uniform syrup-like 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 minute 30 seconds from placement in the oral cavity.

For test purposes, the ratio of powder 1.00g to liquid 0.50g tested at 23±1°C & RH 50±10%.

ISO 9917-1 net setting time: 2 to 8 minutes from start of mix at 36-38°C & RH 90-100%.

(2) PLACEMENT:

Apply the mixed cement immediately on completion of mix, do not overfill. Excess cement may be removed immediately or after cement has set. DO NOT attempt to remove excess cement whilst cement is in the "Rubbery" phase of setting (between 1 minute 30 seconds to 6 minutes from start of mix) as adhesion may be impaired. Wipe the filling instrument/spatula clean immediately.

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 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:



026X2

35g Powder / 21ml Liquid

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.



Advanced Healthcare Ltd., Tonbridge, Kent, TN11 8JU, UK
Tel: +44 1892 870500 Email: sales@ahl.uk.com



Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatara, BKR 4013 Malta.

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