



AHL Generic



GLASS IONOMER LINING MATERIAL (POWDER-LIQUID)

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

DIRECTIONS FOR USE

FEATURES:

Adheres chemically to teeth therefore minimising cavity preparation. Biologically compatible. Thermal expansion coefficient close to enamel and dentine. Non-translucent, radiopaque, it has the consistency of thick cream. Contains fluoride.

INTENDED PURPOSE:

Base or liner under other restorative materials

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:

- Suitable as a base under composite resins or amalgam restorations.

CONTRA-INDICATIONS:

- Pulp capping.

CONTENTS OF PACK:

Powder 10g, liquid 5ml, 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:

Invert powder bottle to "fluff" the powder for accurate dispensing. Take care not to compress powder into scoop. Measure out one scoop and place on a pad or glass slab. When dispensing the liquid, ensure the bottle is held vertically upright. Use a glass slab and a stainless steel spatula for best results. Dispense one drop of liquid. Divide powder into two. Mix the first half for 10 seconds and add remainder. One scoop of powder to one drop of liquid gives the correct 2.75:1 m:m ratio.

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: 3 minutes from placement in the oral cavity.

For test purposes, the ratio of powder 1.10g to liquid 0.40g 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 mixed material to freshly cut cavity. If salivary contamination occurs, cleanse surface with a drop of liquid for 15 seconds, wash and dry using oil-free air, prior to placement of materials.

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:



061XPL 10g Powder/5ml Liquid

COMPOSITION:

Composition	% by weight
Glass powder	50 – 70
Water	10 – 25
Polyacrylic Acid	10 – 20
Tartaric Acid	0 – 5
Reinforcing agents	5 – 15

AHL operates 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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FEEDBACK
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