



AHL Generic



GLASS IONOMER AESTHETIC RESTORATIVE (HUMID STABLE)

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

DIRECTIONS FOR USE

FEATURES:

Adheres chemically to enamel, dentine and cementum. Coefficient of thermal expansion close to tooth. Suitable for use with minimal cavity preparation techniques. A fast setting Glass Ionomer with excellent translucency and optimum aesthetics. Use in ART technique. 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, liquid 5ml, measuring scoop, instructions for use or
Powder 30g, liquid 15ml, 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:

Use minimal tooth reduction whenever possible. Calcium hydroxide liners need only be used in deep cavities. If required, apply Toothcleanser (25% Polyacrylic acid solution) for up to a maximum of 30 seconds. Wash with water and dry with oil-free air.

(2) MIXING:

The recommended powder-liquid ratio is 3:1 mm at 22-24°C and RH 40-60%. Use a clean and dry polished glass slab or paper pad and a stainless steel spatula. Invert bottle to 'fluff' powder for accurate dispensing. Measure TWO level scoops of powder onto glass slab. Dispense ONE 'bubble-free' drop of liquid onto glass slab. Incorporate half the powder into the liquid and mix for 10-15 seconds, then add the remaining powder and spatulate to a uniform putty-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: 3 minutes 30 seconds from placement in the oral cavity.

For test purposes, the ratio of powder 0.90g 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%.

(3) PLACEMENT:

Place into cavity using normal instruments. Avoid contamination of filling with saliva or water during placement.

(4) FINISHING:

Best results are obtained by polishing with abrasive discs or stones at a subsequent visit using water spray lubrication. However, at 7 minutes after placement, the material is hard enough to finish using abrasive discs and stones, but petroleum jelly must be used as a lubricant to prevent excess heat and desiccation of cement. After finishing, it is recommended to coat the surface with light cure glaze or varnish for protection from 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:



261XA1PL	10g Powder Shade A1 / 5ml Liquid
261XA2PL	10g Powder Shade A2 / 5ml Liquid
261XA3PL	10g Powder Shade A3 / 5ml Liquid
261XA3.5PL	10g Powder Shade A3.5 / 5ml Liquid
261XB2PL	10g Powder Shade B2 / 5ml Liquid
261XB4PL	10g Powder Shade B4 / 5ml Liquid
261XC3PL	10g Powder Shade C3 / 5ml Liquid
261XCBPL	10g Powder Shade CB / 5ml Liquid

261XA130	30g Powder Shade A1 / 15ml Liquid
261XA230	30g Powder Shade A2 / 15ml Liquid
261XA330	30g Powder Shade A3 / 15ml 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.



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FEEDBACK
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