

GLASS IONOMER PLUS LUTING CEMENT (POWDER-LIQUID)

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

DIRECTIONS FOR USE

FEATURES:

A radiopaque glass ionomer luting cement with prolonged working time followed by snap-set reaction. Combines good handling, low film thickness, high strength. Good adhesion of porcelain, ceramic or metal to tooth structure. 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:

- Cementing of crowns, bridges, inlays or orthodontic brackets.
- Base liner

CONTRA-INDICATIONS:

Pulp capping.

CONTENTS OF PACK:

Powder 15g, liquid 8ml, 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:

Clean the preparation and restoration with oil-free prophypaste, water and air dry. Use calcium hydroxide if remaining dentin is thin and pulp protection is required.

Place 1 level scoop of powder and 2 bubble-free drops of liquid on glass block or mixing pad and mix thoroughly with flat bladed spatula to creamy consistency.

DO NOT ADD POWDER IN SMALL INCREMENTS.

Total mixing time: 30 seconds

Working time: 3 minutes 30 seconds from start of mix at 23°C.

Setting time: 4 minutes from placement in the oral cavity

For test purposes, the ratio of powder 1.0g to liquid 0.50g 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:

Spread a thin layer of cement over all inside surfaces of restoration and seat on preparation.

(4) FINISHING:

Have patient bite down sufficiently hard on a cotton ball to remove air and trim excess cement squeezed out. The set cement is tooth coloured (U).



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

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 and 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:

REF 201XPL

15g Powder / 8ml 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

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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