MD

AHL Generic CE 0123

RESIN MODIFIED GLASS IONOMER LUTING CEMENT (POWDER-LIQUID)

ISO 9917-2:2017 Resin-modified cements Class 1a

DIRECTIONS FOR USE

FEATURES:
Radiopaque resin modified glass ionomer luting cement with high strength and good aesthetics. Adhesion to metal and 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 all metal, bridges, inlays and onlays.
- Cementing of metal orthodontic brackets to tooth structure.

CONTRA-INDICATIONS:
- Pulp capping.
- Ceramic, Porcelain and Resin, crowns, inlays or onlays not having all-alumina or all-zirconia cores

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) PREPARATION:
- Clean the preparation and restoration with water and dry.
- Use calcium hydroxide if pulp protection is required.
- Do not use eugenol-containing materials.

(2) MIXING:
- Place 1 level scoop of powder and 3 bubble-free drops of liquid on 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: 2 minutes from start of mix at 23°C.
Setting time: 6 minutes from placement in the oral cavity.

For test purposes, the ratio of powder 1.60g to liquid 1.00g 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 layer of cement over all inside surfaces of restoration and place on preparation.

(4) FINISHING:
Trim excess when cement is rubbery.

STORAGE:


Store in a cool, dry place (5-25ºC).
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 and allergic reaction.

BATCH CODE:
LOT 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 299XPL 10g Powder / 5ml Liquid

COMPOSITION:

Composition	% by weight
Glass	60 – 80
Deionised Water	10 - 20
PAA	10 – 20
2-HEMA	5 – 10
Methacrylate resins	1 – 5
Stabiliser	<1
Activators	<1

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
www.ahl.uk.com/feedback