FEEDBACK
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Glass Ionomer Aesthetic Posterior Restorative (Powder/Liquid)

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

DIRECTIONS FOR USE

FEATURES:
A fast setting, high strength glass ionomer restorative with excellent aesthetics. Radiopaque. The cement adheres directly to tooth structure and is especially suited to minimally invasive dentistry. Matches natural fluorescence of enamel. Good for Minimal Intervention (MI) treatment. 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
- Class III cavities.
- Class I and II cavities in deciduous teeth
- Non-load bearing Class I and II cavities in permanent teeth.
- Pits and fissures.
- Core build-up.

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) CAVITY PREPARATION:
Use minimal tooth reduction whenever possible. Calcium hydroxide liners need only to be used in deep cavities. For areas of uncut surfaces, to which adhesion is required, apply Toothcleanser (25% Polyacrylic acid solution) for a *maximum* of 30 seconds using a pled get of cotton wool. Wash with water and dry with oil-free air. In areas, which are heavily coated with plaque or tartar, Prophylaxis with oil free Prophypaste prior to tooth cleansing is required. If freshly cut dentine or enamel is contaminated with saliva, apply Toothcleanser for 10 seconds only before washing with water and drying with oil free air.

(2) MIXING:
The recommended powder-liquid ratio is 2.6:1 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 ONE scoop of powder onto glass slab 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 semi-circular insert. 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: 2 minutes from start of mix at 23°C.
Setting time: 4 minutes from placement in the oral cavity.

For test purposes, the ratio of powder 1.30g 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:
Place into cavity using normal instruments. To avoid material adhering to instruments, dip the clean instrument into the powder or methylated spirit. When using stainless steel matrices, coat lightly with petroleum jelly. The use of coated soft aluminium in the form of either interproximal or cervical matrices is recommended, these do not require lubrication. Avoid contamination of filling with saliva or water during placement. Immediately after removal of matrix, apply a thin layer of light-cured resin with a suitable brush and cure for 10 seconds. Alternatively, a varnish may be used. Re-apply glaze or varnish following any subsequent adjustment to ensure optimum aesthetics.

(4) FINISHING:
Best results are obtained by polishing with abrasive discs or stones at a subsequent visit using water spray lubrication. 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. For optimum polished surface white stones and alumina discs should be used. After finishing, it is recommended to coat the surface with glaze or varnish for protection from moisture.

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.
- Restorations have the potential to fracture depending on patient habits.
- Restorations have the potential to fall out depending on patient habits.

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	AH0100	15g Powder Shade A2 / 7ml Liquid
	AH0101	15g Powder Shade A3 / 7ml Liquid
	AH0102	15g Powder Shade A3.5 / 7ml Liquid

COMPOSITION:

Composition	% by weight
Glass powder	60 – 80
Water	10 - 25
Polyacrylic Acid	10 – 20
Tartaric Acid	0 – 5

MD CE 0123

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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