

AHL Generic (F

GLASS IONOMER AESTHETIC POSTERIOR RESTORATIVE (CAPSULES)

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:

50 capsules, 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 pledget 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:

1. Remove a capsule from an aluminium bag immediately before mixing. Tap gently on a hard surface to loosen any compacted powder.

2. Rotate the plunger clockwise until it stops securely (30°)(Fig.A).

Ensure you do not lift the nozzle before mixing. 3. Press the plunger completely to ensure that all of the liquid is pressed into the

powder (Fig.B)

4. Insert the capsule into the mixer and mix for 10 sec. (frequency: 4000 rpm or more). (Fig.C).

Important- the capsule should not be pressed by the applicator before mixing.

Working time: 1 minute 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 1.30g to liquid 0.50g tested at $23\pm1^{\circ}$ 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%.

Average contents per capsule: 0.27g Powder and 0.11g Liquid. Minimum net volume of mixed cement per capsule: 0.144mL

(3) PLACEMENT:

1. After mixing, remove the capsule from the mixer immediately. Then, place it into the applicator.

2. Lift the nozzle completely to dispense the paste (Fig.D).

If the nozzle is not lifted completely, the paste cannot be dispensed correctly. 3. Dispense and apply the material to the restoration within 30 seconds after mixing.



(4) FINISHING:

Best results are obtained by polishing with abrasive discs or stones at a subsequent visit using water spray lubrication. It is possible to start the finishing and contouring process after 3 minutes from start of mixing but optimum aesthetics and hardness are achieved after 7 minutes from start of mixing. It is recommended to use petroleum jelly 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:



Visc 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 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:

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
 276XA2CAP

 276XA3CAP
 276XA3CAP

 276XA3.5CAP
 276XA3.5CAP

Shade A2 Shade A3 Shade A3.5

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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