



AHL Generic



GLASS IONOMER SILVER REINFORCED RESTORATIVE (POWDER-LIQUID)

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

DIRECTIONS FOR USE

FEATURES:

Adheres chemically to tooth substance and set amalgam. Low thermal conductivity and coefficient of thermal expansion is close to tooth. Radiopaque, non-translucent. High compressive strength and hardness. Smooth polishable surface. Suitable for use with minimal cavity preparation techniques. Suitable for use with 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 I and II in deciduous and posterior permanent teeth.
- Base under amalgam and posterior composite restorations.
- In cavities where radiopacity is the prime requirement.
- As a core build up
- Temporary replacement for cusp(s)

CONTRA-INDICATIONS:

- Pulp capping.

CONTENTS OF PACK:

117XPL – powder 10g, liquid 7ml, measuring scoop, instructions for use
117XPLJ – powder 30g, liquid 10ml, 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. 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. As freshly cut dentine or enamel is often contaminated with saliva, always apply Toothcleanser for 10 seconds immediately prior to placement. Wash with water and dry with oil-free air.

(2) MIXING:

The powder:liquid ratio is 7.3:1 mm. 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 2 scoops onto glass slab taking care not to compress powder against side of bottle with the scoop. Remove excess from scoop using a straight edge of a spatula. Dispense 1 drop of 'bubble-free' 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 stiff uniform putty-like consistency.

DO NOT ADD POWDER IN SMALL INCREMENTS.

Total mixing time: 30 seconds.

Working time: 1 minute 45 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 1.10g to liquid 0.15g 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:

Condense the material into cavity using normal instruments. To avoid material adhering to instruments, dip the clean instrument into methylated spirit. When using stainless steel matrix bands around class II cavities, coat lightly with petroleum jelly. The use of coated soft aluminium in the form of either interproximal strips or preformed cervical matrices is recommended; neither require lubrication. Avoid contamination 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, using a surgery light at 470nm for 10 seconds. Alternatively, a varnish can be used. Re-apply glaze or varnish following any subsequent adjustment to ensure maximum protection.

The surface may be carved and contoured using the conventional instruments that are employed with amalgam. This must NOT go beyond the end of the working time when the cement begins to harden.

(4) FINISHING:

It is hard enough to withstand the use of rotary instruments after 7 minutes. Trimming and contouring. Removal of appreciable quantities of the set cement is best accomplished with sandpaper discs, stainless steel burs, or green stones in a low speed handpiece. Petroleum jelly should be applied to prevent frictional heating and consequent desiccation.

Final adjustment of the surface is best carried out using white Stones or alumina discs. With glass ionomer, a better polish is obtained at a subsequent visit. The best results are obtained using Shofu Greenies or Super-Snap green discs. At whatever stage the finishing process is completed, it is recommended to coat the surface with glaze or varnish.

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:



117XPL 10g Powder / 7ml Liquid
117XPLJ 30g Powder / 10ml Liquid

COMPOSITION:

| Composition | % by weight |
|-------------------|-------------|
| Glass powder | 50 – 70 |
| Water | 5 – 15 |
| Polyacrylic Acid | 10 – 20 |
| Tartaric Acid | 0 – 5 |
| Reinforcing agent | 10 – 20 |

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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