



AHL Generic



Glass Ionomer Ceramic Reinforced EXTRA (POWDER-LIQUID)

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

DIRECTIONS FOR USE

FEATURES:

Glass Ionomer Ceramic Reinforced Extra is an advanced posterior restorative material that is radiopaque and has high strength. It bonds chemically to enamel, dentine and cementum. Suitable for use with ART Technique Repair of amalgam restored teeth when either tooth or restoration has fractured. Passes the tests in the Amalgam normative standard ISO 24234:2004. Translucent. 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 all classes of cavity where radiopacity is a prime requirement.
- As a core build up
- Long term temporary replacement for cusps(s).

CONTRA-INDICATIONS:

- Pulp capping.

CONTENTS OF PACK:

Powder 12g, 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 wherever possible.
- Calcium hydroxide liners need only be used in deep cavities.
- Tooth Cleanser (25% polyacrylic acid solution) is applied to areas of unreduced tooth, to which adhesion is required, using a pledget of cotton wool for a maximum of 30 seconds.
- Wash with water and dry with oil-free air.
- If freshly cut enamel or dentine is contaminated with saliva, Tooth Cleanser should be applied but only for 10 seconds before washing is started.

(2) MIXING:

- Powder liquid ratio 3.6:1 m:m
- Use a glass block for best results and a stainless steel spatula
- Dispense two level scoops of powder onto a glass block / mixing pad.
- Then, dispense one drop of bubble free liquid
- Incorporate half the powder into the liquid as quickly as possible (5-10 seconds) and then add the remainder and spatulate to a THICK putty-like consistency.

DO NOT ADD POWDER IN SMALL INCREMENTS.

Total mixing time: 30 seconds.

Working time: 1 minute 30 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 0.72g to liquid 0.20g 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:

- Apply to cavity using normal instruments (non-stick aluminium instruments are particularly suitable).
- If problems of cement adhering to the steel instrument occur, dip the clean instrument either into the powder or methylated spirit.
- If stainless steel matrices are used, they should be lightly coated with petroleum jelly.

(4) FINISHING:

- Best results are obtained by polishing with abrasive discs and 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 the cement.
- After finishing, the surface should be coated with varnish for protection from moisture.

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:



393XPL 12g Powder / 5ml Liquid

COMPOSITION:

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