



# AHL Generic



## ZINC POLYCARBOXYLATE CEMENT (POWDER/LIQUID)

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

### DIRECTIONS FOR USE

#### FEATURES:

Adhesive to enamel, dentine and non-precious metals and giving rise to minimal pulpal reaction. Radiopaque, non-translucent. 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:

- Cementation of crowns, bridges, inlays, and onlays.
- Cementation of orthodontic bands
- Base/lining under composite, amalgam or glass-ionomer
- Temporary filling.

#### CONTRA-INDICATIONS:

- Pulp capping.

#### CONTENTS OF PACK:

078XPL – powder 90g, liquid 30ml, measuring scoop, instructions for use

078X2 – powder 90g, measuring scoop, instructions for use

011X6 – liquid 30ml, instructions for use

#### PRECAUTIONS AND WARNINGS:

- Liquid contains polyacrylic acid.
- Avoid contact with skin, oral mucosa and eyes.
- In the event of contact rinse with copious quantities of water and seek medical assistance.
- Do not expose patients or users known to be allergic to this type of material.

#### PROCEDURE

##### (1) PREPARATION:

- Clean the preparation and restoration with oil-free prophypaste, water and air dry.
- Invert the powder bottle to fluff the contents, this ensures correct scoop weight.
- Lightly fill the scoop with powder - do NOT compress against side of the bottle. Remove excess powder with a flat spatula blade.
- To dispense accurate drops of liquid, hold the bottle vertically and squeeze gently.

##### (2) MIX RATIO:

Cementation: 1 scoop powder: 2 drops liquid (powder: liquid ratio 2.6:1 mm)

Base/Liner/Temporary Filling: 1 scoop powder: 1 drop liquid (ratio 5.2:1 mm)

##### (2) MIXING:

- Incorporate the powder into the liquid in three increments at 10 second intervals, and spatulate thoroughly.
- The consistency of the cementation mix is that of thick cream, and the higher ratio is that of a putty.
- Mix at 22-24°C.
- For best results, a clean, dry glass slab and stainless steel spatula should be used.

#### DO NOT ADD POWDER IN SMALL INCREMENTS.

**Total mixing time:** 30 seconds.

**Working time:** 1 minute 10 seconds from start of mix at 23°C.

**Setting time:** 7 minutes from placement in the oral cavity.

For test purposes, the ratio of powder 1.50g to liquid 0.30g tested at 23±1°C & RH 50±10%.

ISO 9917-1 net setting time: 2 to 8 minutes from start of mix at 36-38°C & RH 90-100%.

##### (3) PLACEMENT:

- For cementation apply to restoration and seat as quickly as possible.
- As base or restorative, place in cavity in thick section.
- Excess cement may be removed immediately or when hardened.
- Clean instruments immediately on completion.

#### 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.

#### 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:



078XPL	90g Powder / 30ml Liquid
078X2	90g Powder
011X6	30ml Liquid

#### COMPOSITION:

Composition	% by weight
Zinc Oxide	50 – 70
Magnesium Oxide	5 – 15
Stannous Fluoride	1 – 10
Polyacrylic acid	5 – 15
Deionised Water	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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