



# AHL Generic



## ZINC POLYCARBOXYLATE CEMENT (WATER MIX)

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

### DIRECTIONS FOR USE

#### FEATURES:

A Zinc Polycarboxylate cement. Adhesive to enamel, dentine and non-precious metals and giving rise to minimal pulpal reaction. Mixes with water for ease and convenience of use. 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:

- Restorative cementation of crowns, bridges, inlays and onlays.
- Orthodontic cementation of bands.
- Base/Lining under composite, amalgam or glass ionomer.
- Temporary Filling.

#### CONTRA-INDICATIONS:

- Pulp capping.

#### CONTENTS OF PACK:

Powder 50g, measuring scoop, water dispensing bottle, dropper tip, instructions for use

#### PRECAUTIONS AND WARNINGS:

- Powder 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.

##### (2) MIX RATIO:

Cementation: 1 scoop powder: 3 drops water 5:1 m:m.

Base/Liner/Temporary Filling: 1 scoop powder: 2 drops water 7.5:1 m:m.

##### (2) MIXING:

- Lightly fill the scoop with powder - do NOT compress against wall of the bottle.
- Strike off excess powder with a spatula blade.
- Dispense onto pad or glass slab.
- Hold water bottle vertically and squeeze gently to dispense water drops onto slab.
- Incorporate the powder into the water quickly, in two increments, and spatulate thoroughly.

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

**Total mixing time:** 30 seconds.

**Working time:** 1 minute 50 seconds from start of mix at 23°C.

**Setting time:** 6 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 6 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; leaving the mix to stand for about thirty seconds before insertion reduces the tendency to stick to placement instruments.

#### STORAGE:



Store in a cool, dry place (5-25°C).

Always replace cap immediately after use.

Water uptake in humid conditions can adversely affect the properties.

#### 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:



079X1

50g Powder

#### COMPOSITION:

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

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.



Advanced Healthcare Ltd., Tonbridge, Kent, TN11 8JU, UK

Tel: +44 1892 870500 Email: [sales@ahl.uk.com](mailto:sales@ahl.uk.com)



Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.

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