



AHL Generic



ZOE TEMPORARY LUTING CEMENT

DIRECTIONS FOR USE

FEATURES:

This product is designed for first aid only and professional treatment should be sought as soon as possible. It is not a permanent filling material and recommended use is up to a maximum of 4 weeks.

INTENDED PURPOSE:

Temporarily 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 the general public.

CLINICAL BENEFIT:

To restore the function of the teeth and help maintain the integrity of the remaining tooth structure.

INDICATIONS FOR USE:

- Temporary cementing of crowns, bridges, inlays, onlays and splints
- Temporary Cavity Filling.

CONTRA-INDICATIONS:

- Contains eugenol and should not be used on patients with a known allergy to eugenol.
- Eugenol inhibits the polymerisation of resin based materials avoid using these materials after the use of this temporary cement.
- Do NOT use for anything other than listed in the indications.

CONTENTS OF PACK:

Catalyst paste 5g, base paste 10g, instructions for use.

PRECAUTIONS AND WARNINGS:

- These products shall not be placed in contact with pulp tissue.
- Direct exposure of these products may harm the pulp.
- Avoid prolonged contact with skin, eyes, and soft tissue.
- Wash thoroughly with water after contact.
- Catalyst contains eugenol.
- IRRITANT.
- Avoid contact with skin and eyes.
- Do not expose patients or users known to be allergic to this type of material.

PROCEDURE

(1) REPLACING DISLODGED CROWNS AND BRIDGES:

(a) PREPARATION:

- Wash hands thoroughly.
- Remove any old cement from around the tooth / teeth and the inside (fitting) surfaces of the crown / bridge.
- Rinse the mouth and crown / bridge free of food or other debris using water and a toothbrush if available.
- Check seating of crown / bridge is still ok.

(b) MIXING:

- Measure equal lengths of catalyst and base pastes (2cm approx.) onto a clean mixing surface and mix thoroughly.

Total mixing time: 20 seconds.

Working time: 40 seconds from start of mix at 23°C.

Setting time: 5 minutes from placement in the oral cavity.

(c) PLACEMENT:

- Transfer some of the fluid mixed cement to the inside (fitting) surfaces of the crown / bridge and re-seat in the mouth as quickly as possible.

(d) FINISHING:

- After 5 mins, any excess cement may be trimmed CAREFULLY from the margin of the crown / bridge.
- Allow 1 hour after repair before eating.

(2) REPLACING LOST FILLING OR BROKEN TOOTH:

(a) PREPARATION:

- Wash hands thoroughly.
- Rinse the mouth free from food or other debris using water and a toothbrush if available.

(b) MIXING:

- Measure equal lengths of catalyst and base pastes (2cm approx.) onto a clean mixing surface and mix thoroughly.

Total mixing time: 20 seconds.

Working time: 40 seconds from start of mix at 23°C.

Setting time: 5 minutes from placement in the oral cavity.

(c) PLACEMENT:

- Leave the mixed cement to stand for 2-5 mins.
- During this time the cement will become stiff and putty-like in texture.
- Roll the putty-like cement into a ball using a clean finger and thumb.
- Press the cement into the cavity ensuring all gaps are filled.
- Smooth the surface of the cement quickly if necessary.

(d) FINISHING:

- After a further 3 minutes, any excess cement may be trimmed CAREFULLY from the surrounding tooth surface.
- Allow 1 hour after repair before eating.

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:



312X1

1 x Catalyst Paste 5g Tube and 1 x Base Paste 10g Tube

COMPOSITION:

Composition	% by weight
Zinc Oxide	20 – 40
Eugenol	1 – 5
Solvents	30 – 50
Pigments	0 – 5
Fillers	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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