



AHL Generic



ROOT CANAL SEALANT (ZINC OXIDE EUGENOL)

ISO 6876:2012 Root canal sealing materials

DIRECTIONS FOR USE

FEATURES:

A paste-paste zinc oxide eugenol cement for use with obturation points. The 2 pastes mix easily to a smooth creamy consistency with long working time and setting time. The cement has moderate flow characteristics, is radiopaque and has a low in film thickness.

INTENDED PURPOSE:

Endodontic sealer

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:

- Permanent obturation of the root canal space with the aid of obturation points.

CONTRA-INDICATIONS:

- Zinc oxide eugenol based sealants in general may produce periapical inflammation in the first few days after placement.
- Such inflammation should subside naturally as healing progresses.
- There are no known systemic side-effects to date.
- However, some people may exhibit sensitivity to eugenol.
- If any such reactions are experienced, discontinue use of product and seek medical assistance.

CONTENTS OF PACK:

Base paste 8g, catalyst paste 3.5g, mix pad, instructions for use.

PRECAUTIONS AND WARNINGS:

- These products shall not be placed in contact with pulp tissue.
- Avoid prolonged contact with skin, eyes, and soft tissue.
- Wash thoroughly with water after contact.
- 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) MIXING:

- Squeeze equal lengths of base paste and catalyst paste on pad and mix thoroughly with flat bladed spatula to creamy consistency of uniform colour.
- Base Paste 2cm line (0.33g)
- Catalyst Paste 2cm line (0.15g)

Total mixing time: 20 seconds.

Working time: 30 minutes from start of mix at 23°C.

Setting time: more than 30 minutes from placement in the oral cavity.

(2) PLACEMENT:

- Coat the obturation point with cement.
- Spread a layer of cement over all inside surfaces of root canal using an appropriate carrier (e.g. endodontic file, gutta percha or paper point).
- Seat obturation point slowly using normal procedures.

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 and 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:



398X1 8g Base Paste / 3.5g Catalyst Paste

COMPOSITION:

Composition	% by weight
Zinc Oxide	40 – 60
Solvents	30 – 50
Pigment	1 – 5
Eugenol	1 – 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 above address stating the batch number shown on the packaging.

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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FEEDBACK
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