



AHL Generic



HIGH VISCOSITY TEMPORARY FILLING MATERIAL

DIRECTIONS FOR USE

FEATURES:

A ready to use temporary filling material with a synthetic resin base. Easily packable consistency with little or no tendency to stick to instruments. Adequate strength yet easily removed. Good sealing characteristic, easy to use consistency.

INTENDED PURPOSE:

Temporary restoration of lost tooth structure.

INTENDED PATIENT POPULATION:

From child to geriatrics

INTENDED USER:

This product has been formulated for use in dentistry and can be use by dental professionals or the general public.

CLINICAL BENEFIT:

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

INDICATIONS FOR USE:

- Temporary filling of cavities
- Temporary sealing of inlay preparations

CONTRA-INDICATIONS:

- Do not use for more than 4 weeks
- Any Purpose not Indicated above.

CONTENTS OF PACK:

226X1 30g jar, instructions for use
226X2 7g tube, instructions for use

PRECAUTIONS AND WARNINGS:

- Do not expose users known to be allergic to this type of material.
- To avoid infection and/or serious injury, this product should not be used if there is throbbing pain, ulceration or swelling in the affected area.
- If any of these symptoms exist, consult your dentist immediately.
- This product should not be placed on open wounds.
- READ ALL OF THE DIRECTIONS CAREFULLY BEFORE USE!
- Wash and dry your hands.
- Do not get unused cement wet.
- Use only what is needed to repair the dental emergency.
- KEEP OUT OF REACH OF CHILDREN.
- DO NOT use product for any purpose other than indicated.
- You should consult a dentist within 24 hours of applying this product.
- Temporary filling material is only used as a temporary solution.
- Due to sensitivity to moisture, close the tube or jar immediately after removing the material, since otherwise the viscosity of the material increases (due to the entry of moisture), and the material may no longer be extractable.

PROCEDURE

(1) PLACEMENT:

- Using a suitable filling instrument, place direct into cavity and adapt as necessary.
- It is not essential to dry the cavity prior to placement.
- Temporary filling material hardens by absorption of moisture to give an impermeable seal.
- For provisional fixing of post crowns spread a layer on inside of crown and seat in normal way.
- Do not chew for the next 2 hours.
- For tube presentation, remove cap from tube, reverse and pierce membrane fully.
- Use key provided to assist extrusion from tube.

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:



226X1 30g Jar
226X2 7g Tube

COMPOSITION:

Composition	% by weight
Calcium Sulphate	50 – 60
Barium Sulphate	10 – 20
Glycol Ether	10 – 20
Zinc Oxide	5 – 15
Acrylic Polymer	0 – 5
Potassium Sulphate	0 – 5
Silica	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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