



# AHL Generic



## INJECTABLE HYBRID RESTORATIVE MATERIAL

ISO 4049:2019 Polymer based restorative materials

### DIRECTIONS FOR USE

#### FEATURES:

An advanced light-curable radiopaque flowable restorative material indicated for anterior and posterior restoration. Contains fluoride.

#### INTENDED PURPOSE:

Restoration of lost tooth structure

#### 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:

- Anterior and posterior restorations.
- Repairs of restorations and prostheses.

#### CONTRA-INDICATIONS:

Do not use this product for any purposes other than specifically outlined under INDICATIONS in these instructions for use

#### CONTENTS OF PACK:

Syringe 2g, Tips x 5, Instructions for use

#### PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material and/or methacrylate monomers.
- If any eruption or skin inflammation occurs on a patient when using this product, immediately discontinue use and have the patient seek medical advice.
- Avoid contacting oral mucosa, skin or eyes. In case of contact, rinse immediately with copious amounts of water and seek medical advice.
- If a cavity is deep, protect with a pulp capping agent. (N.B. Do not use a eugenol containing liner).
- Wear UV protective glasses when light curing.
- When storing these materials in a refrigerator, allow them to reach room temperature before use

#### PROCEDURE

##### (1) CAVITY PREPARATION:

- Thoroughly clean the tooth surface to remove plaque.
- Select appropriate shade using a shade guide while the tooth is still moist.
- Prepare the cavity in the conventional way.
- If the pulp is exposed or is close to the restoration, then a calcium hydroxide liner should be used. (N.B. Do not use a eugenol containing liner).
- Apply the bonding agent according to the manufacturer's directions.
- AHL Generic Etch Gel & Bonding Agent is recommended (code: 071X1 & 250X1) for use in cavities.

##### (2) PLACEMENT:

- Dispense the required amount of material from the syringe using a clean needle tip.
- Always replace the syringe cap after use.
- After placing and contouring the restoration, cure with a light unit.

##### (3) CURING

- Select the light curing time in the table below.
- Light cure the entire surface of the restoration.
- For deep cavities, the layering technique is recommended, Place in a layer of up to 2mm depth and cure with a dental light cure unit.

Light Curing Unit	LED curing unit	Halogen lamp curing unit
Light Curing Time	10 seconds	20 seconds
Wavelength	440-490 nm	400-500 nm
Light Intensity	≥ 1000 mW/cm <sup>2</sup>	≥ 500 mW/cm <sup>2</sup>

- Use a dental light-curing unit having specifications equivalent to those described above.
- When using a unit having performance other than these recommendations, follow the instructions for that unit

##### (4) FINISHING:

- After curing, remove excess material with abrasive stones and points and then polish.

#### SINGLE USE



Discard the tip after use.  
This must not be re-used on another patient for hygienic reasons.

#### STORAGE:



Store in a cool, dry place (1-30°C).  
Always replace cap immediately after use.  
Keep away from direct sunlight

#### 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.
- Restorations have the potential to fracture depending on patient habits.
- Restorations have the potential to fall out depending on patient habits.

#### 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:



UL422A1/1	- 2g Syringe A1
UL422A2/1	- 2g Syringe A2
UL422A3/1	- 2g Syringe A3
UL422A3.5/1	- 2g Syringe A3.5
UL422A4/1	- 2g Syringe A4
UL422B2/1	- 2g Syringe B2
UL422A10/1	- 2g Syringe A10
UL422A20/1	- 2g Syringe A20
UL422INC/1	- 2g Syringe INC

#### COMPOSITION:

Composition	% by weight
Filler	50 – 80
Methacrylate resins	20 – 50
Initiators	<1
Stabilisers	<1
Pigments	<1
Other	<1

Particle Range: 0.01 to 2.0µm – Mean Particle Size: 0.8µm

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, Swatara, BKR 4013 Malta.

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