



# AHL Generic



## UNIVERSAL LIGHT-CURE COMPOSITE RESTORATIVE

ISO 4049:2019 Polymer based restorative materials

### DIRECTIONS FOR USE

#### FEATURES:

##### (1) COMPOSITE:

An advanced composite for both anterior and posterior use. Good wear resistance, aesthetics and radiopacity twice that of dentine. Available in 13 shades. Contains fluoride.

##### (2) ETCH GEL:

Optimum viscosity for easy extrusion with thixotropic 'non-drip' effect to remain where applied. Syringe presentation for ease of application. Bright colour to ensure precise placement is achieved.

##### (3) BONDING ADHESIVE:

A solvent-free, visible light curing Single Component Bonding Adhesive for enamel and dentine. It has a distinctive ability to moisten and penetrate the dentine. The product is a viscous non-thixotropic liquid. Only one application is needed – combines bonding agent and primer in a one part formula. It is not compromised if the dentine is wet or dry, etched or unetched. Exhibits under various operational conditions an appropriate adhesion for composites and compomers to enamel and dentine as well as ensuring long lasting strong marginal adaptation.

#### 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 cavities I, II, III, IV and V.
- Wedged shaped defects and root caries.
- Direct laminate veneers.
- Core build ups.
- Repair of fractured laminate veneer.

#### CONTRA-INDICATIONS:

- Use on exposed pulp
- Use on pulpitis

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

#### CONTENTS OF PACK:

Single use capsules x 20, Etch gel 5ml, Bonding Adhesive 5ml, instructions for use  
Syringe 4g, Etch gel 5ml, Bonding Adhesive 5ml, instructions for use

#### PRECAUTIONS AND WARNINGS:

- Do not expose patients or users known to be allergic to this type of material.
- 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.
- This product has been formulated for use in dentistry and is intended for use by dental professionals only.
- Causes burns.
- In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).
- Secure cap immediately after use.
- Do not force plunger; if blocked, replace tip.
- Do not reuse tip.
- Harmful if swallowed.
- May cause sensitisation by skin contact
- When storing these materials in a refrigerator, allow them to reach room temperature before use

#### PROCEDURE

##### (1) CAVITY PREPARATION:

- After cleaning the tooth surface and while the tooth is still moist check the shade.
- Prepare the cavity in the conventional way, employing a bevelled edge where appropriate. If the pulp is exposed or is close to the restoration, then a calcium hydroxide liner should be used.

##### (2) ETCHING:

- Syringe the etch-gel directly on to the enamel surfaces to be treated.
- The gel can be spread using the Syringe tip or any other suitable instrument (small ball-ended plugger or brush).
- Leave etch gel in place for 30 seconds. Wash and dry using oil-free air. Enamel surface should have a dull frosted appearance. If not, repeat procedure as above.

##### (3) BONDING:

- Dispense a sufficiently thick layer of Bonding Adhesive onto the etched enamel and dentine.
- With a brush or a cotton applicator tip, massage the Bonding Adhesive into the tooth for 20 seconds to achieve an even, glossy layer.
- Cure with a halogen light for 15 – 30 seconds. (The longer curing time is recommended to ensure total curing right down into the dentine tubules).

##### (4) PLACEMENT:

- Dispense the required amount of material from the syringe or capsule. If using the syringe, release pressure immediately after dispensing by turning the syringe handle counterclockwise 360°. Always replace the syringe cap after use. Part used capsules should be discarded.

##### (5) CURING

- After placing and contouring the restoration, cure with a light unit.
- 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

##### (6) FINISHING:

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

#### SINGLE USE



The capsule may only be used once due to hygienic reasons (prevention of cross-contamination between patients).

#### STORAGE:



**COMPOSITE:**  
Keep away from direct sunlight  
store at room temperature (1 - 30°C).



**BONDING ADHESIVE:**  
Store in a cool dry place. Do not expose to direct sun light or other heat sources. If room temperature is likely to exceed 25°C storage in a refrigerator is recommended. Do not freeze.



**ETCH GEL:**  
Store in a cool dry place (5-25°C).

#### 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:



248X2A1 -	20 x 0.25g Capsule A1
248X2A2 -	20 x 0.25g Capsule A2
248X2A3 -	20 x 0.25g Capsule A3
248X2A3.5 -	20 x 0.25g Capsule A3.5
248X2A4 -	20 x 0.25g Capsule A4
248X2B2 -	20 x 0.25g Capsule B2
248X2C2 -	20 x 0.25g Capsule C2.2
248X2BW -	20 x 0.25g Capsule BW
248X2A2O -	20 x 0.25g Capsule A2O
248X2A3O -	20 x 0.25g Capsule A3O
248X2INC -	20 x 0.25g Capsule INC

248X3A1 -	4g Syringe A1
248X3A2 -	4g Syringe A2
248X3A3 -	4g Syringe A3
248X3A3.5 -	4g Syringe A3.5
248X3A4 -	4g Syringe A4
248X3B2 -	4g Syringe B2
48X3C2 -	4g Syringe C2
248X3BW -	4g Syringe BW
248X3A2O -	4g Syringe A2O
248X3A3O -	4g Syringe A3O
248X3INC -	4g Syringe INC

071X1	5ml Blue Etch Gel Syringe & Tips
250X1	5ml Bonding Adhesive Bottle

**COMPOSITION:**  
**ETCH:**

Composition	% by weight
Phosphoric Acid	35 – 45
Deionised Water	50 – 60
Silica	1 – 10
Solvent	0 – 5
Pigment	0 – 5
Xanthan Gum	<1

**BONDING AGENT:**

Composition	% by weight
Polyacrylic acid	0 – 5
Methacrylate Resins	60 – 80
2-HEMA	15 – 25
Initiators	1 – 5
Stabilisers	<1
Water	0 – 10

**COMPOSITE:**


Composition	% by weight
Filler	60 – 80
Methacrylate resins	10 – 30
Initiators	<1
Stabilisers	<1
Pigments	<1
Other	<1


Particle Range: 0.01 to 5.0µm – Mean Particle Size: 1.0µm

*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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