MD

AHL Generic CE 0123

UNIVERSAL LIGHT-CURE COMPOSITE RESTORATIVE

ISO 4049:2019 Polymer based restorative materials

DIRECTIONS FOR USE

FEATURES:
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.

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:
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, instructions for use
Syringe 4g, 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.
- 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.
- Apply the bonding agent according to the manufacturer's directions. AHL Etch Gel & Bonding Agent are recommended (code: 071X1 & 250X1).

(2) 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.

(3) 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^2	≥ 500 mW/cm^2

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

STORAGE:
Store in a cool, dry place (1-30ºC).
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.
- Restorations have the potential to fracture depending on patient habits.
- Restorations have the potential to fall out depending on patient habits.

BATCH CODE:
LOT 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:

REF

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 C22
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

COMPOSITION:

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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FEEDBACK
www.ahl.uk.com/feedback