MD

AHL Generic CE 0123

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. Two different flowabilities, F00 and F03 are available. F00 exhibits minimal flowability, while F03 exhibits slight flowability.

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.
- 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:
- 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.
- 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.
- Always replace the syringe cap after use.

(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	30 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
Discard the tip after use.
This must not be re-used on another patient for hygienic reasons.

STORAGE:
Store in a cool, dry place (1-30ºC).
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 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

F00	
UL421A1/1	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
UL422A1O/1	2g Syringe A1O
UL422A2O/1	2g Syringe A2O
UL422INC/1	2g Syringe INC
F03	
UL421A2/1	2g Syringe A2
UL423A3/1	2g Syringe A3
UL423A3.5/1	2g Syringe A3.5
UL421B2/1	2g Syringe B2
UL423A3O/1	2g Syringe A3O

COMPOSITION:

Composition	% by weight
Filler	55 – 85
Methacrylate resins	10 – 45
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.

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FEEDBACK
www.ahl.uk.com/feedback