



AHL Generic



Bulk Fill Composite Restorative

ISO 4049:2019 Polymer based restorative materials

DIRECTIONS FOR USE

FEATURES:

An advanced composite predominantly designed for posterior use, including occlusal surfaces. High wear resistance, optimum translucency for aesthetic appearance and high level of radiopacity. Low polymerisation shrinkage. Can be placed in 4mm layers. 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:

- Direct Posterior Restorations

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 4g, 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.
- Monomers may pass through dental gloves; avoid material contact for maximum protection.
- 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.
- 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. After using the syringe, release pressure immediately after dispensing by turning the syringe handle counter-clockwise 360°.
- Always replace the syringe cap after use.
- Place in a layer of up to 4mm depth and cure with a dental light cure unit.

(3) CURING

- Select the light curing time in the table below.

Shade	Depth of cure	LED curing unit	Halogen lamp curing unit
		Wavelength 440-490 nm	Wavelength 400-500 nm
Universal	4 mm	Light Intensity $\geq 1000 \text{ mW/cm}^2$	Light Intensity $\geq 500 \text{ mW/cm}^2$
		10 seconds	20 seconds

- 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; contour, finish and polish using conventional methods.

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:



411XU	-	4g Syringe Shade Universal
411XA	-	4g Syringe Shade A

COMPOSITION:

Composition	% by weight
Filler	70 – 90
Methacrylate resins	10 – 30
Initiators	<1
Stabilisers	<1
Pigments	<1
Other	<1

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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