

Prior to use, carefully read
the instructions for use. EN**G-aenial Universal Injectable**

UNIVERSAL LIGHT-CURED RADIOPAQUE INJECTABLE COMPOSITE

For use only by a dental professional in the recommended indications.

INDICATIONS FOR USE

1. Direct restorative for Class I, II, III, IV and V cavities
2. Fissure sealant
3. Sealing hypersensitive areas
4. Repair of (in)direct aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel
5. Blocking out undercuts
6. Liner or base

CONTRAINDICATIONS

1. Direct pulp capping.
2. Avoid use of this product in patients with known methacrylate monomer or methacrylate polymer allergies.

OPERATION

1. Preparations

- 1) Hold the syringe upright and remove the wing cap by turning counterclockwise.
 - 2) Promptly and securely attach the dispensing tip to the syringe by turning clockwise.
 - 3) Place the light protective cap until use.

Note:
Take care not to attach the dispensing tip too tightly. This may damage its screw. In order to ensure a tight connection make sure that the threads are free of remnant material.

2. Shade Selection

Select shade from 16 shades of XBW, BW, A1, A2, A3, A3.5, A4, B1, B2, CV, CVD, AO1, AO2, AO3, JE, AE.

A, B, C, D shades are based on Vita® Shade.

3. Cavity Preparation

Prepare cavity using standard techniques. Dry by gently blowing with oil free air. Rubber dam is recommended to isolate the prepared tooth from contamination with saliva, blood or sulcus fluid.

Note:

For pulp capping, use calcium hydroxide.

4. Bonding Treatment

For bonding G-aenial Universal Injectable to enamel and/or dentin, use a light-cured bonding system such as G-Premio BOND, G-aenial Bond or G-BOND. Follow manufacturer's instructions.

5. Placement of G-aenial Universal Injectable

- 1) Remove cap from the dispensing tip.

Note: Prior to dispensing the material into the cavity, make sure to check the following:

- 1) Dispensing tip is securely attached to the syringe.
 - 2) Any possible air from the dispensing tip is removed by gently pushing forward the syringe plunger with the tip pointing upwards until material reaches the opening of the tip (Fig. 2).
 - 3) Place the dispensing tip as close as possible to the prepared cavity, and slowly push the plunger to extrude material. Alternatively, dispense material onto a mixing pad and transfer to the cavity using a suitable instrument.
 - 4) After use, immediately remove and dispose of the dispensing tip and tightly close the syringe with the wing cap.

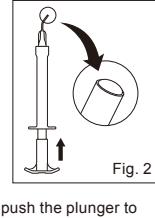
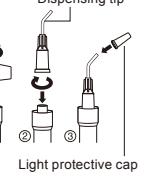


Fig. 2

Clinical Hints

In order to inject effectively, use the surface tension of the material to ensure uniformity across the entire surface of the restoration during build up. Once the required amount has been injected, release the pressure on the plunger and withdraw the syringe in a direction perpendicular to the surface. This will allow the material to separate from the dispensing tip and provides a smooth surface over the restoration.

6. Light-curing

Light-cure G-aenial Universal Injectable using a light curing unit. Keep light guide as close as possible to the surface. Refer to the following chart for Irradiation Time and Effective Depth of Cure.

	10 sec. (High power LED) (>1200mW/cm²)	20 sec. (Halogen/LED) (>700 mW/cm²)
A1, A2, A3, B1, B2, JE, AE	2.5mm	
XBW, BW, A3.5, A4, A01, A02, CV, CVD	2.0mm	
A03	1.5mm	

Note:

1. Material should be placed and light-cured in layers. For maximum layer thickness, please consult above table.

2. Lower light intensity may cause insufficient curing or discoloration of the material.

7. Finishing and Polishing

Finish and polish using standard techniques.

SHADES

XBW, BW, A1, A2, A3, A3.5, A4, B1, B2, CV, CVD, AO1, AO2, AO3, JE, AE

STORAGE

Recommended for optimal performance, store in a cool and dark place (4-25°C/39.2-77.0°F) away from high temperatures or direct sunlight. (Shelf life: 3 years from date of manufacture)

PACKAGES

1. Syringe 1.7g (1.0mL) x1, Dispensing Tip Needle x5, Dispensing Tip Long Needle x5, Light-protective cap x1
2. Syringe 1.7g (1.0mL) x2, Dispensing Tip Needle x10, Dispensing Tip Long Needle x10, Light-protective cap x2
3. Dispensing Tip Refill: Dispensing Tip Long Needle x30, Light-protective cap x2

CAUTION

1. In case of contact with oral tissue or skin, remove immediately with cotton or a sponge soaked in alcohol. Flush with water. To avoid contact, a rubber dam and/or cocoa butter can be used to isolate the operation field from the skin or oral tissue.
2. In case of contact with eyes, flush immediately with water and seek medical attention.
3. Take care to avoid ingestion of the material.
4. Do not mix with other similar products.
5. Dispensing tips are for single use only. To prevent cross contamination between patients, do not reuse the dispensing tip. The dispensing tip cannot be sterilized in an autoclave or chemidate.
6. Wear plastic or rubber gloves during operation to avoid direct contact with air inhibited resin layers in order to prevent possible sensitivity.
7. Wear protective eye glasses during light curing.
8. When polishing the polymerised material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.
9. Avoid getting material on clothing.
10. In case of contact with unintended areas of teeth or prosthetic appliances, remove with instrument, sponge or cotton pellet before light-curing.
11. Do not use G-aenial Universal Injectable in combination with eugenol containing materials as eugenol may hinder G-aenial Universal Injectable from setting.
12. Do not wipe the dispensing tip with excessive alcohol as this may cause contamination of the paste.
13. Dispose of all wastes according to local regulations.
14. In rare cases the product may cause sensitivity in some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.
15. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.

Some products referenced in the present IFU may be classified as hazardous according to GHS. Always familiarise yourself with the safety data sheets available at: <http://www.gcamerica.com> They can also be obtained from your supplier.

CLEANING AND DISINFECTION:
MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged.

DO NOT IMMERSER. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level registered healthcare-grade infection control product according to regional/national guidelines.

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Rx Only

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the instructions for use. FR**G-aenial Universal Injectable**COMPOSITE INJECTABLE UNIVERSEL PHOTOPOLYMERISABLE
RADIOOPAQUE

Ce produit est réservé aux professionnels dentaires selon les recommandations d'utilisation

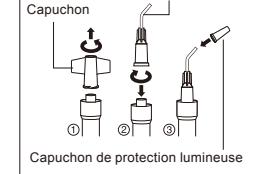
- INDICATIONS – RECOMMANDATIONS**
1. Restoration directe de petite cavité de classe I, IV, III, II et V
 2. Serrage des fissures
 3. Serrage des zones hypersensibles
 4. Réparation des restaurations esthétiques directes et indirectes, couronne et bridge temporaire, défauts marginaux lorsque les bords sont dans l'émail.
 5. Comblement de contre-dépouille
 6. Liner ou base

CONTRE-INDICATIONS

1. Coiffage pulpaire direct
2. Ne pas utiliser ce produit chez les patients présentant une allergie connue au monomère ou polymère méthacrylates.

APPLICATION

1. Préparation
2. Tenez la seringue verticalement et retirez le capuchon en tournant dans le sens inverse des aiguilles d'une montre.
3. Fixez rapidement et solidement l'embout de mélange à la seringue en tournant dans le sens des aiguilles d'une montre.
4. Placez le Capuchon de protection contre la lumière jusqu'à l'utilisation.



Note : Prenez garde de ne pas trop serrer l'embout de mélange. Cela pourrait endommager la vis.

Afin d'assurer une étroite connexion, assurez-vous que les filetages sont exempts de résidus de matériaux.

2. Sélection de la teinte

Sélectionnez la teinte appropriée parmi les 16 teintes : XBW, BW, A1, A2, A3, A3.5, A4, B1, B2, CV, CVD, AO1, AO2, AO3, JE, AE.

Vita® est une marque déposée de Vita Zahnfabrik, Bad Säckingen, Allemagne.

3. Préparation de la cavité

Préparez la cavité en utilisant les techniques standards. Séchez doucement avec de l'air propre sans trace d'eau. Une ligne en caoutchouc est recommandée pour isoler la dent préparée des risques de contamination par la salive, le sang et les fluides du sucre.

Note : Vita® est une marque déposée de Vita Zahnfabrik, Bad Säckingen, Allemagne.

4. Collage

Pour coller G-aenial Universal Injectable à l'émail et / ou à la dentine, utilisez un système de collage photopolymérisable comme G-Premio BOND, G-aenial Bond ou G-BOND. Siga las instrucciones del fabricante.

5. Placement du G-aenial Universal Injectable

- 1) Retirez le capuchon

Note : Avant d'utiliser le matériau, assurez-vous :

1. Que l'embout de distribution est bien attaché à la seringue.
2. De supprimer l'air présent dans l'embout en poussant doucement le piston de la seringue vers le haut, jusqu'à ce que le matériau atteigne l'ouverture (Fig. 2).

2) Placez l'embout le plus près possible de la cavité préparée et appuyez doucement sur le piston. Vous pouvez également extraire le matériau sur un bloc de mélange et le transférer dans la cavité avec un instrument adapté.

Note :

a. Si l'embout est bouché, retirez-le pour extraire une petite quantité de matériau directement de la seringue.

b. Minimisez l'exposition à la lumière. La lumière ambiante peut raccourcir le temps de manipulation.

c. Après utilisation, retirez aussitôt l'embout de mélange et refermez hermétiquement avec le capuchon de la seringue.

Astuce clinique

Pour injecter efficacement, utilisez la tension de surface du matériau afin d'assurer une uniformité sur la surface entière de la restauration au cours de la réalisation. Une fois la quantité souhaitée injectée, relâchez la pression sur le piston et retirez la seringue en restant perpendiculaire à la surface. Cela permettra au matériau de se séparer de l'embout et d'offrir une surface lisse à la restauration.

6. Photopolymérisation

Photopolymériser G-aenial Universal Injectable avec une unité de photopolymérisation.

Gardez l'embout lumineux le plus près possible de la surface. Se référer au tableau des temps d'irradiation et des profondeurs de polymérisation.

Temps d'irradiation et profondeur de polymérisation (ISO 4049)

	10 sec. (Puissance élevée LED) (>1200mW/cm²)	20 sec. (Halogène/LED) (>700 mW/cm²)

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