

Prior to use, carefully read
the instructions for use.

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G-aenial™ BULK Injectable

UNIVERSAL LIGHT-CURED RADIOPAQUE INJECTABLE COMPOSITE FOR BULK FILL RESTORATION

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
7. Core build-up

CONTRAINDICATIONS

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

DIRECTIONS FOR USE

1. Shade Selection Select an appropriate shade of G-aenial BULK Injectable.
2. 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.

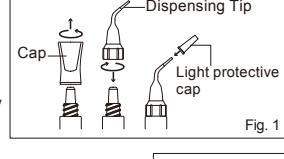
3. Bonding Treatment

For bonding G-aenial BULK 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.

4. Placement of G-aenial BULK Injectable

1) Dispensing from a syringe

1. Hold the syringe upright and remove the cap by turning counter-clockwise (Fig. 1).
2. Promptly and securely attach the dispensing tip to the syringe by turning clockwise.



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

3. Place the light protective cap until use.
4. Remove cap from the dispensing tip.

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

- a. Dispensing tip is securely attached to the syringe.
- b. Any possible air from the dispensing tip is removed by gently pushing forward the syringe plunger with the lip pointing upwards until material reaches the opening of the tip (Fig. 2).

5. 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.

Note:

- a. If plugged, remove the dispensing tip and extrude a small amount of material directly from the syringe.
- b. Minimize exposure to ambient light. Ambient light can shorten the working time.
- c. After use, immediately remove and dispose of the dispensing tip and tightly close the syringe with the cap.

2) Dispensing from a Unitip

Insert the G-aenial BULK Injectable Unitip into the Unitip APPLIER II or equivalent. Remove the cap and extrude material directly into the prepared cavity. Use steady pressure (Fig. 3). Maintain pressure on the applier handle while removing the Unitip APPLIER II and Unitip from the mouth. This prevents the Unitip from coming loose from the applier.

Note:
The material may be hard to extrude immediately after removing from cold storage. Prior to use, leave to stand for a few minutes at room temperature.**Clinical Hints**

In order to inject effectively, 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.

Light-curing

Light-cure G-aenial BULK Injectable using a light curing unit with a minimum intensity of 1,200 mW/cm² for 20 seconds. G-aenial BULK Injectable can be filled and cured in a single bulk increment depth of up to 4 mm. Keep light guide as close as possible to the surface.

Irradiation Time and Effective Depth of Cure

	Irradiation time	20 sec. (High power LED) (more than 1200 mW/cm ²)	30 sec. (Halogen/LED) (700-1200 mW/cm ²)
Shade	A1, A2	4.0 mm	

Finishing and Polishing

Finish and polish using standard techniques.

SHADES

A1, A2

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.

PACKAGES

I. Syringes

1. Syringe 3.4 g (2.0 mL) x 1, DISPENSING TIP III (plastic) x 20, Light-protective cap x 1
2. Dispensing Tip Refill: 30 DISPENSING TIP III (plastic type), 2 light protective cap 30 DISPENSING TIP III (needle type), 2 light protective cap

II. Unitips

1. Unitip 0.27 g (0.16 mL) x 15

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. Prior to starting the filling process, partially extrude paste outside of the patient's mouth and away from the patient to ensure paste is flowing properly.
5. Do not mix with other similar products.
6. 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 chemilavative.
7. For infection control reasons, Unitips are for single use only.
8. Wear plastic or rubber gloves during operation to avoid direct contact with air inhibited resin layers in order to prevent possible sensitivity.
9. Wear protective eye glasses during light curing.
10. When polishing the polymerized material, use a dust collector and wear a dust mask to avoid inhalation of cutting dust.
11. Avoid getting material on clothing.
12. In case of contact with unintended areas of tooth or prosthetic appliances, remove with instrument, sponge or cotton pellet before light-curing.
13. Do not use G-aenial BULK Injectable in combination with eugenol containing materials as eugenol may hinder G-aenial BULK Injectable from setting.
14. Do not wipe the dispensing tip with excessive alcohol as this may cause contamination of the paste.
15. Dispose of all wastes according to local regulations.
16. 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.
17. 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 familiarize 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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G-aenial™ BULK InjectableCOMPOSITE UNIVERSEL PHOTOPOLYMERISABLE ET
RADIO-OPAQUE INJECTABLE POUR OBTURATIONS EN MASSE

Réserve à l'utilisation par un professionnel dentaire conformément aux indications recommandées.

DIRECTIVES D'UTILISATION

1. Matériau de restauration directe pour les cavités de classes I, II, III, IV et V
2. Scellant pour fissures
3. Scellage des zones hypersensibles
4. Réparation des restaurations esthétiques directes ou indirectes, des couronnes et ponts provisoires, des défauts des bords lorsque les bords arrivent au niveau de l'email
5. Blocage des zones de contre-dépouille
6. Base ou doubleur
7. Reconstitution coronaire

CONTRE-INDICATIONS

1. Coiffage pulinaire direct
2. Eviter d'utiliser ce produit sur les patients présentant une allergie connue au monomère de méthacrylate ou au polymère de méthacrylate.

MODE D'EMPLOI

1. Sélection de la teinte Sélectionner la teinte appropriée de G-aenial BULK Injectable.
2. Préparation de la cavité Préparer la cavité à l'aide des techniques courantes. Assécher délicatement à l'aide d'un essuie huile. L'utilisation d'une dique est recommandée pour protéger la dent préparée de la contamination par la salive, le sang ou le fluide gingival.

Note:

Pour le coiffage pulinaire, utiliser de l'hydroxyde de calcium.

3. Traitement adhésif

Pour le collage de G-aenial BULK Injectable à l'email ou à la dentine, utiliser un système adhésif photopolymérisable tel que G-Premio Bond, G-aenial Bond ou G-Bond. Suivre les directives du fabricant.

4. Mise en place de G-aenial BULK Injectable

- 1) Avec une seringue

1. Tenir la seringue en position verticale et retirer le capuchon en le tournant dans le sens antihoraire (Fig. 1).

2. Fixer rapidement et solidement l'embout distributeur à la seringue en tournant dans le sens horaire.

Note:
Prendre soin de ne pas fixer l'embout distributeur de manière trop serrée. Cela pourrait endommager la vis. Afin de garantir un raccordement serré, s'assurer que le filtre de la seringue n'est pas déposé.

3. Placer le capuchon filtrant jusqu'au moment de l'utilisation.

4. Retirer le capuchon de l'embout distributeur.

Note:
Avant d'appliquer le matériau à la seringue dans la cavité, vérifier les éléments suivants:

a. L'embout distributeur est solidement fixé à la seringue.

b. Tout l'air a été retiré de l'embout distributeur en poussant délicatement le piston de la seringue avec l'extrémité de la seringue pointant vers le haut, jusqu'à ce que le matériau atteigne l'ouverture de l'extrémité (Fig. 2).

2) Avec un Unitip

Insérer G-aenial BULK Injectable dans son applicateur ou équivalent. Retirer le capuchon et extraire le matériau directement dans la cavité préparée. Appliquer une pression constante (Fig. 3). Maintenir la pression sur la manette de l'applicateur pendant le retrait de l'Unitip de la bouche et de l'applicateur. Cela pour éviter que l'Unitip ne se détache.

Note:
Il peut être difficile d'extraire le matériau lorsqu'il est froid. Dans ce cas laissez à température ambiante pendant quelques minutes avant utilisation.

Trucs cliniques

Pour injecter le matériau de manière efficace, assurer une application uniforme sur toute la surface de la restauration au moment de réaliser la reconstruction. Une fois la bonne quantité injectée, relâcher la pression sur le piston et retirer la seringue en direction perpendiculaire à la surface. Cela permet au matériau de se séparer de l'embout applicateur et fournit une surface uniforme sur la restauration.

5. Photopolymérisation

Photopolymériser le G-aenial BULK Injectable au moyen d'une lampe à polymérisation d'une intensité minimale de 1200 mW/cm² durant 20 secondes. G-aenial BULK Injectable peut être appliqué et photopolymérisé en une seule masse d'une profondeur maximale de 4 mm. Maintenir le guide lumineux de la lampe à polymériser aussi près que possible de la surface.

Temps d'irradiation et profondeur de polymérisation efficace

	Temps de polymérisation	20 sec. (Puissance élevée LED) (plus de 1200 mW/cm ²)	30 sec. (Halogène/LED) (700-1200 mW/cm ²)
Tonos	A1, A2	4.0 mm	

6. Finition et polissage

Procéder à la finition et au polissage en suivant les techniques courantes.

TEINTES

A1, A2

ENTREPOSAGE

Pour un rendement optimal, entreposer dans un endroit frais et sombre (4-25 °C/39.2-77.0 °F) à l'abri des températures élevées et des rayons directs du soleil.

CONDITIONNEMENT

I. Seringues