

Prior to use, carefully read
the instructions for use

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G-aenial® Universal Injectable
UNIVERSAL LIGHT-CURED RADIOPAQUE INJECTABLE
COMPOSITE

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

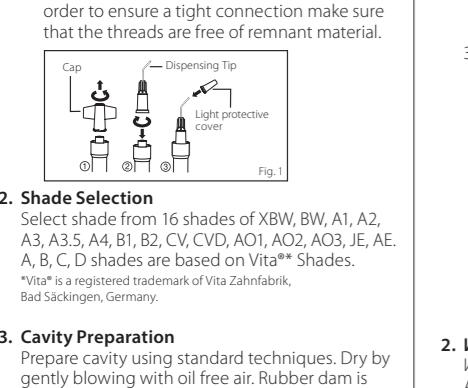
RECOMMENDED INDICATIONS

- Direct restorative for Class I, II, III, IV and V cavities
- Fissure sealant
- Sealing hypersensitive areas
- Restorative and aesthetic restorations, temporary crown & bridge, defect margins when margins are in enamel
- Blocking out undercutts
- Liner or base
- Restoration of crowns & bridges, inlays and veneers using the indirect technique with composite resin in G-C GRADIA or G-C GRADIA PLUS components (please refer to their dedicated IFU).
- Splitting of teeth in combination with fibres such as GC everStick fibres. Follow manufacturer's instructions.

CONTRAINdications

- Holding the syringe upright and remove the wing cap by turning counter-clockwise.
- Promptly and securely attach the dispensing tip to the syringe by turning clockwise.
- Place the light protective cover until use.

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



2. Shape Selection

Select shape from 16 shades of XBW, BW, AI, A2, A3, A3.5, A4, B1, B2, CV, CVD, AO1, AO2, AO3, JE, AE, A, B, C. D shades are based on "Vita" Shades. "Vita" is a registered trademark of Vita Zahnfabrik, Bad Säckingen, Germany.

3. Cavity Preparation

Prepare cavity using standard techniques. Dry by gently blowing with air free of bubbles before recommended to isolate the prepared tooth from contamination with saliva, blood or sputum fluid.

Note: For pulp capping, use calcium hydroxide.

4. Bonding Treatment

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

5. Placement of G-aenial Universal Injectable

- Remove cover from the dispensing tip.

Note: Prior to checking the cavity, make sure to check the following:

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

2) 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 required, remove the dispensing tip and extrude a small amount of material directly from the syringe.
b. Minimal exposure to ambient light. Ambient light can shorten the manipulation time.
c. After use, immediately remove and dispose of the dispensing tip and tightly close the syringe with the wing cap.

Clinical Hint: 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 dispensed, release the pressure on the plunger and turn the dispensing tip 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 (ISO 4049)

	10 sec. (High power LED (> 1200mW/cm ²)	
	20 sec. (Halogen/LED (> 700mW/cm ²)	
A1, A2, A3, B1, B2, JE, AE	2,5 mm	
XBW, BW, A3.5, A4, AO1, AO2, CV, CVD	2,0 mm	

Note:

- Material should be placed and light-cured in layers. For maximum layer thickness, please consult above table.
- Lower light intensity may cause insufficient curing or discoloration of the material.

For the indirect technique light-cure each layer for 30 seconds with GC LABOLIGHT LV-III or for 10 seconds with GC STEPLIGHT SL-I. Final cure for 3 minutes using GC LABOLIGHT LV-III.

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, JE, AE

STORAGE

Recommended for optimal performance, store in a cool and dark place (-4° - 25°C) away from high temperature or direct sunlight.

(Shelf life: 3 years from date of manufacture)

PACKAGES

1. Syringe 1.7 (1.0mL) x1, Dispensing Tip Long Needle x10, Light-protective cover x1

2. Dispensing Tip Long Needle x10, Light-protective cover x30

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 chemical.

6. Wear plastic or rubber gloves during operation to avoid direct contact with air infused resin layers on the restoration. Use clean water to wash off any residue from the glove.

7. In case of contact with eyes, flush immediately with water and seek medical attention.

8. Take care to avoid ingestion of the material.

9. After use, immediately remove and dispose of the dispensing tip and tightly close the syringe with the wing cap.

10. Remove all wastes according to local regulations.

11. 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.

12. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.

Some products referred in the present IFU may be considered as hazardous.

13. Always familiarise yourself with the safety data sheet available.

14. <http://www.geceurope.com>

They can also be obtained from your supplier.

CLEANING AND DISINFECTION:

MUST-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 IMMERSIVE: Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with mid-level registered healthcare-grade infection control product according to regional/national guidelines.

Last revised: 03/2018

1. Тысячелитровая инъекционная система для вспомогательных инъекций.

2. G-aenial® Universal Injectable

УНИВЕРСАЛЬНЫЙ ФОТОПОЛИМЕРИЗУЮЩИЙ РЕНТИНОКОНТАКТНЫЙ ТЕЧЕНЫЙ КОМПОЗИТ

За употреба само от дентални специалисти за претпоправки на индикации:

ПРЕПОРЪЧВАННИ ИНДИКАЦИИ

1. Директен възстановяване на кавити клас I, II, III, IV и V.

2. Силиконизиране на фисури.

3. Затваряне на отвори във външни области.

4. Изграждане на (пол)директни естетични възстановявания, временни коронки и мостове, дефекти на ръбове, когато границите са в емайла.

5. Затваряне на подмолни.

6. Подложка или основа.

7. Изграждане на външни корове и фасети, чрез използване на индикаторна техника в комбинация с GRADIA или GRADIA PLUS (моля, вижте специализираните инструкции за употреба).

8. Шиниране на зъби в комбинация с влакна, напр. GC everStick fibres. Следвате инструкции на производителя.

КОНТРАИНДИКАЦИИ

1. Директно пълнително покритие.

2. Изграждане на употребата на този продукт при пациенти с известни алергии на метакрилатни мономери и полимери.

ПРОЦЕДУРА

1. Подготовка

1) Държете шприцата изправена и отстранете капачката чрез затваряне на спускача.

2) Установете подмолни.

3) Поставете външният коров на подложка.

4) Изграждане на мостове и коронки.

5) Изграждане на временни мостове и коронки.

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