

G-aenial A'CHORD™
LIGHT-CURED RADIOPAQUE COMPOSITE
RESTORATIVE

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

INDICATIONS FOR USE

- Direct restorative for Class I, II, III, IV and V cavities.
- Direct restorative for wedge-shaped defects and root surface cavities.
- Direct restorative for veneers and diastema closure.

CONTRA-INDICATIONS

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

COMPOSITION

Banum glass, dimethylacrylate, silicon dioxide, initiator, pigment, stabilizer

DIRECTIONS FOR USE

- Shade Selection
- Wet the material with purified water. Shade selection should be made prior to solation.
- Select the appropriate G-aenial A'CHORD shades by referring to the color chart in the section "G-aenial A'CHORD Core shades". Core shades were developed to match several Vita shades as described in the below table. Stratification is of course an option as well. Please refer to the section "CLINICAL TIPS" on stratification advice.

Shade correspondence between VITA® Classic Shade and G-aenial A'CHORD Core shade

VITA® Classic Shade	G-aenial A'CHORD Core shade	VITA® Classic Shade
A1	A1	A1
A2	A2	A2
A3	A3	A3
A3.5	A3.5	A2
A4	A4	B2
B1	A1	C1
B2	A2	D3
B3	A3	A3
B4	A3.5	B9
C1	A2	C2
C3	A3	A4
C4	A3.5	A5
D1	A1	A5
D3	A2	B4
D4	A3	C4
D5	A4	A4

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.europeurope.com> or <http://www.gamerica.com>. They can also be obtained from your supplier.

CLEANING AND DISINFECTION:

MULTI-USE DELIVERY SYSTEMS: To avoid cross-contamination, clean this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if DO NOT IMMERSE. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level registered healthcare-control product according to regional/national guidelines.

For the Summary of Safety and Clinical Performance (SSCP) please see EUADAMED database (<http://ec.europa.eu/tools/eudamed>) or contact us at Regulatory@gecgec.dental.

UNDESIGNED EFFECTS - REPORTING:

If you become aware of any kind of undesigned effect, reaction or similar events experienced by use of this product, report them directly to the relevant authority for use, please report them directly through the relevant vigilance system, by selecting the proper authority of your country accessible through the following link: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en, as well as to our internal vigilance system: <http://www.gamerica.com>. In this way you will contribute to improve the safety of this product.

Last revised : 06/2023

UK Responsible Person

GC UNITED KINGDOM Ltd.

Coopers Court Newport Pagnell

Buckinghamshire

MK16 8JS

United Kingdom

Vor der Benutzung bitte die Geleitunterlagen lesen.

DE

G-aenial A'CHORD™
LIGHT-CURED RADIOPAQUE RESTORATIVES RESTAURATIONS-KOMPOSIT

Darf nur von zahnärztlichem Fachpersonal in den angegebenen Indikationen verwendet werden.

ANWENDUNGSHINWEISE

- Direkte Restauratoren der Kavitätenklassen I, II, III, IV.
- Restauratoren von körnigen Defekten und Wurzel-Oberflächenkavitäten.
- Restauratoren von Veneers und zum Diastemanchluss.

ZUSAMMENSETZUNG

Bariumglas, dimethylacrylat, siliciumdioxid, Initiator, pigment, Stabilisator

KONTRAINDIKATIONEN

- Direct pulp capping.
- Verhindern Sie die Verwendung dieses Produkts bei Patienten mit Allergien gegen Methacrylat-Monomer oder Methacrylat-Polymer.

1. Dispensing from a syringe: remove the cap and dispense material onto a mixing pad.

Note: After dispensing, screw syringe plunger counter-clockwise by half a turn to fully release residual pressure inside the syringe. Replace cap immediately after use.

The dispensing unit must be cleaned immediately after removing from cold storage. Prior to use leave to stand for a few minutes.

After dispensing, and extended exposure to ambient light, Ambient light can shorten the manipulation time.

2. For pulp capping, use calcium hydroxide.

3. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1). Follow manufacturer's instructions.

4. Placement of G-aenial A'CHORD

5. Dispensing from a syringe: remove the cap and dispense material onto a mixing pad.

Note: After dispensing, screw syringe plunger counter-clockwise by half a turn to fully release residual pressure inside the syringe. Replace cap immediately after use.

The dispensing unit must be cleaned immediately after removing from cold storage. Prior to use leave to stand for a few minutes.

After dispensing, and extended exposure to ambient light, Ambient light can shorten the manipulation time.

3. Cavity Preparation

Prepare cavity using standard techniques. Dry by gently blowing off with dry air.

Note: For pulp capping, use calcium hydroxide.

4. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

5. Placement of G-aenial A'CHORD

6. Direct pulp capping:

Insert the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

7. For pulp capping, use calcium hydroxide.

8. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

9. Placement of G-aenial A'CHORD

10. Direct pulp capping:

Insert the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

11. For pulp capping, use calcium hydroxide.

12. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

13. Placement of G-aenial A'CHORD

14. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

15. For pulp capping, use calcium hydroxide.

16. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

17. Placement of G-aenial A'CHORD

18. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

19. For pulp capping, use calcium hydroxide.

20. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

21. Placement of G-aenial A'CHORD

22. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

23. For pulp capping, use calcium hydroxide.

24. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

25. Placement of G-aenial A'CHORD

26. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

27. For pulp capping, use calcium hydroxide.

28. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

29. Placement of G-aenial A'CHORD

30. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

31. For pulp capping, use calcium hydroxide.

32. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

33. Placement of G-aenial A'CHORD

34. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

35. For pulp capping, use calcium hydroxide.

36. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

37. Placement of G-aenial A'CHORD

38. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

39. For pulp capping, use calcium hydroxide.

40. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

41. Placement of G-aenial A'CHORD

42. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

43. For pulp capping, use calcium hydroxide.

44. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

45. Placement of G-aenial A'CHORD

46. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

47. For pulp capping, use calcium hydroxide.

48. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin, using a light-cured bonding system such as G-Premio BOND, G-BOND, G-BOND (Fig. 1).

Follow manufacturer's instructions.

49. Placement of G-aenial A'CHORD

50. Light curing:

Place the G-aenial A'CHORD Untip into the Untip APPLIer or equivalent. Remove the cap and dispense material onto the prepared cavity. Use steady pressure. Maintain pressure on the applicator handle while removing the Untip APPLIer and Unite from the mouth. This prevents the Untip from coming loose from the applicator.

51. For pulp capping, use calcium hydroxide.

52. Bonding treatment: use a light-cured A'CHORD to enamel and / or dentin

