

Prior to use, carefully read the instructions for use. **EN**

GRADIA™ gum shades

LIGHT-CURED GUM SHADE COMPOSITE SYSTEM

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

INDICATIONS FOR USE

Reproduction of gum tissue for crown restorations, such as implant superstructures and removable metal frames.

CONTRAINDICATIONS

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

DIRECTIONS FOR USE

For the following steps (No.1-5) of the procedure, refer to GRADIA instructions for use.

1. Procedure of Metal Framework
 - 1) Wax up framework in usual manner.
 - 2) Cast in usual manner.
 - 3) Using a carbide bur, adjust casting in usual manner.
2. Treatment of Metal Framework
 - 1) Sandblast retention area using 50 to 110 micron aluminum oxide.
 - 2) Clean with dry, oil-free air.
 - 3) Application of Metal PRIMER II / METALPRIMER Z

Apply one or two thin coats of METALPRIMER II / METALPRIMER Z to the retention area.
 Note : After application of the METALPRIMER II / METALPRIMER Z, immediately start to apply GRADIA OPAQUE to avoid contamination of the retention area.

4. Application and Light curing of GRADIA FOUNDATION OPAQUE
 Apply a layer of GRADIA FOUNDATION OPAQUE to the retention area to mask the metal colour. Light cure for 1 minute using the LABOLIGHT LV-III / LABOLIGHT DUO.
 Note : The STEPLIGHT SL-I / LABOLIGHT DUO cannot be used for light curing GRADIA FOUNDATION OPAQUE.

5. Build-up of veneer crown
 Apply GRADIA composite and light cure according to GRADIA instructions for use.

6. Application and Pre-light curing of Gum Opaque (GO)
 Apply two thin layers of Gum Opaque (GO) to the gum part of the metal framework. Temporarily light cure each layer for 1 minute using the LABOLIGHT LV-III / LABOLIGHT DUO.
 Note : 1) For light curing refer to the following chart of irradiation time and Depth of cure.

2) For colour adjustment, apply Gum Opaque Modifier (GOM51) to the light cured Gum Opaque. Light cure for 1 minute using the LABOLIGHT LV-III / LABOLIGHT DUO.

3) The STEPLIGHT SL-I / LABOLIGHT DUO cannot be used for light curing Gum Opaque and Gum Opaque Modifier.
 7. Application, Pre-curing and Final curing of Gum (G)
 Apply Gum (G). Temporarily light cure for 30 seconds using the LABOLIGHT LV-III / LABOLIGHT DUO or for 10 seconds using the STEPLIGHT SL-I / LABOLIGHT DUO or for 3 minutes using the LABOLIGHT LV-III / LABOLIGHT DUO.
 Note :

1) If gum application exceeds the depth of cure mentioned in the chart, finish in layers and light cure respectively (in the LABOLIGHT LV-III / LABOLIGHT DUO).

2) In case of long span restorations, apply in sections to each side of one tooth and carry out final cure respectively in order to minimise curing shrinkage.

3) Apply Gum Modifier (GM) or Gum Translucent (GT) as necessary.
 4) If it is desired to reproduce blood vessels in the gum area, incorporate Gum Fiber (GF71) in translucent Gum Modifier (GM30) or material of another shade, mix, apply and light cure.

5) When using Gum Fiber, cover with Gum Translucent. Light cure two or three minutes.

8. Removal of air inhibited layer and Shape adjustment
 Remove air inhibited layer and adjust contour using a carbide bur, diamond point or carbondrum point.

9. Finish
 Leave the margin thicker than desired and progressively finish using a rubber point or silicone point.

10. Polish and buff
 Polish and buff in usual manner to complete the gum restoration.

Irradiation time for Gum Opaque, Gum Opaque Modifier

Light curing device	Pre-cure	Final cure
LABOLIGHT LV-III, II / LABOLIGHT DUO	1 min.	—
Halogen / High power LED	20 sec.	—

Note :
 1) The STEPLIGHT SL-I / LABOLIGHT DUO cannot be used to light cure the above materials.
 2) When using a hand held type light curing device*, apply light in all directions for complete polymerization.

Irradiation time for Gum, Gum Modifier, Gum Translucent

Light curing device	Pre-cure	Final cure
LABOLIGHT LV-III, II / LABOLIGHT DUO	30 sec.	3 min.
STEPLIGHT SL-I / LABOLIGHT DUO	10 sec.	—
Halogen / High power LED	20 sec.	1 min.

Note :
 1) The STEPLIGHT SL-I / LABOLIGHT DUO cannot be used for final curing.
 2) When using a hand held type light curing device*, apply light in all directions for complete polymerization.

Depth of cure (using the LABOLIGHT LV-III / LABOLIGHT DUO)

Irradiation time	Pre-cure (30 sec.)	Pre-cure (1 min.)	Final cure (3 min.)
Shades	—	0.2 mm	—
Gum Opaque	—	0.2 mm	—
Gum	1.1 mm	—	2.5 mm
Gum Modifier	0.8 mm	—	1.5 mm
Gum Translucent	3.0 mm	—	5.0 mm

Note :
 The depths of cure for translucent Gum (G20) and Gum Modifier (GM30) are equivalent to that of Gum Translucent.

STORAGE
 Recommended for optimal performance, store in a cool place away from direct sunlight.

SHADES & PACKAGES (GRADIA gum shades)

1. Starter Package
 - a. Gum Opaque (G011, G012 or G013) 1
 - Syringe of 2.4mL solution - Gum Opaque (G011) 1
 - Syringe of 2.4mL solution - Gum Opaque (G013) 1
 - Syringe of 2.9mL paste - Gum (G21) 1
 - Syringe of 2.9mL paste - Gum (G22) 1
 - Syringe of 2.9mL paste - Gum (G23) 1
 - Syringe of 2.9mL paste - Gum (G24) 1
 - Syringe of 2.4mL gel - Gum Translucent (G14) 1
 - Dispensable palette 1
 - Light protective cover 1
 - Mixing pad No. 22 1
 - Brush No. 7 1
 - Shade guide kit 1
 - Color chart 1
2. Refill Packages
 - a. Gum Opaque (G011, G012 or G013) 1
 - Syringe of 2.4mL solution 1
 - b. Gum Opaque Modifier (GOM51) 1
 - Syringe of 2.4mL solution 1
 - c. Gum (G20, G21, G22, G23 or G24) 1
 - Syringe of 2.9mL paste 1
 - d. Gum Modifier (GM30, GM31, GM32, GM33, GM34, GM35 or GM36) 1
 - Syringe of 2.4mL gel 1
 - e. Gum Translucent (G14) 1
 - Syringe of 2.4mL gel 1
 - f. Gum Fiber (GF71) 1
 - Bottle of 0.4g fibers 1

CAUTION
 1. In case of contact with oral tissues or skin, remove immediately with a sponge or cotton soaked in alcohol. Flush with water.
 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. If material is stored in a refrigerator, remove from refrigerator and leave to stand at room temperature for at least 30 minutes before use.
 5. After dispensing material, use as quickly as possible. Be sure to remove any residual material from the tip of the syringe and replace cap immediately after use.
 6. Do not mix with other materials.
 7. When light curing material, be sure to follow the irradiation time described in the above-mentioned chart. Do not use ultraviolet lights or visible light curing devices that can radiate ultraviolet light.
 8. When light curing material, do not look directly into the light.
 9. When adjusting or polishing composite resin, use a dust collector and wear a dust mask to avoid inhaling dust.
 10. The brush can be cleaned with alcohol after use.
 11. In rare cases the product may cause sensitivity to some persons. If such reactions are experienced, discontinue 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 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.gceurope.com>
 or for The Americas
<http://www.gcamerica.com>
 They can also be obtained from your supplier.

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

Undesired effects - Reporting:
 If you become aware of any kind of undesired effect, reaction or similar events experienced by use of this product, including those not listed in this instruction 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: vigilance@gce.dental
 In this way you will contribute to improve the safety of this product.

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 Last revised: 10/2022

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GRADIA™ gum shades

LICHTHÄRTENDES ZAHNFLEISCHFARBENES KOMPOSITSYSTEM

Nur von zahnärztlichem / zahnärztlichem Fachpersonal für die genannten Anwendungsgebiete zu verwenden.

INDIKATIONEN ZUR ANWENDUNG

Reproduktion von Zahnfleisch / implantatgetragenen Suprastrukturen und herausnehmbarem Zahnersatz.

GEGENANZEIGEN

Dieses Produkt darf nicht an Patienten verwendet werden, die eine Allergie gegen Methacrylatmonomer oder Methacrylatpolymer haben.

GEBRAUCHSANWEISUNG

Für die folgenden Schritte (Nr.1-5) bitte auch die Gebrauchsanweisung für GRADIA beachten.

1. Herstellung von herausnehmbarem Zahnersatz
 - 1) Zunächst wie gewohnt aufwachsen.
 - 2) Daraufhin einen Abdruck erstellen.
 - 3) Mit einem Polierer den Abdruck entsprechend anpassen.
2. Behandlung des metallischen Trägers
 - 1) Die Retention im Aluminiumoxid 50 bis 110 Micron Korngröße sandstrahlen.
 - 2) Anschließend mit trockener und ölfreier Druckluft reinigen.

3. Anwendung von METALPRIMER II / METALPRIMER Z
 Die Retentionsfläche mit einem oder zwei dünnen Überzügen von METALPRIMER II / METALPRIMER Z versehen.
 BEMERKUNG :
 Unmittelbar nach der Anwendung von METALPRIMER II / METALPRIMER Z mit dem Auftrag von GRADIA OPAQUE beginnen, um eine zwischenzeitliche Verunreinigung der Retentionsfläche zu vermeiden.
 Aufbringen und Licht härten von GRADIA FOUNDATION OPAQUE
 Die Retentionsfläche des Gerüsts abdecken, wird eine Schicht GRADIA FOUNDATION OPAQUE auf die Retentionsfläche aufgebracht und anschließend eine Minute lang mit dem LABOLIGHT LV-III / LABOLIGHT DUO gehärtet.

4. Anwendung und Vorlicht härten von Gum Opaque (GO)
 Apply two thin layers of Gum Opaque (GO) to the gum part of the metal framework. Temporarily light cure each layer for 1 minute using the LABOLIGHT LV-III / LABOLIGHT DUO.
 Note : 1) For light curing refer to the following chart of irradiation time and Depth of cure.

2) For colour adjustment, apply Gum Opaque Modifier (GOM51) to the light cured Gum Opaque. Light cure for 1 minute using the LABOLIGHT LV-III / LABOLIGHT DUO.

3) The STEPLIGHT SL-I / LABOLIGHT DUO cannot be used for light curing Gum Opaque and Gum Opaque Modifier.
 7. Application, Pre-curing and Final curing of Gum (G)
 Apply Gum (G). Temporarily light cure for 30 seconds using the LABOLIGHT LV-III / LABOLIGHT DUO or for 10 seconds using the STEPLIGHT SL-I / LABOLIGHT DUO or for 3 minutes using the LABOLIGHT LV-III / LABOLIGHT DUO.
 Note :

1) If gum application exceeds the depth of cure mentioned in the chart, finish in layers and light cure respectively (in the LABOLIGHT LV-III / LABOLIGHT DUO).

2) In case of long span restorations, apply in sections to each side of one tooth and carry out final cure respectively in order to minimise curing shrinkage.

3) Apply Gum Modifier (GM) or Gum Translucent (GT) as necessary.
 4) If it is desired to reproduce blood vessels in the gum area, incorporate Gum Fiber (GF71) in translucent Gum Modifier (GM30) or material of another shade, mix, apply and light cure.

5) When using Gum Fiber, cover with Gum Translucent. Light cure two or three minutes.

8. Removal of air inhibited layer and Shape adjustment
 Remove air inhibited layer and adjust contour using a carbide bur, diamond point or carbondrum point.

9. Finish
 Leave the margin thicker than desired and progressively finish using a rubber point or silicone point.

10. Polish and buff
 Polish and buff in usual manner to complete the gum restoration.

Irradiation time for Gum Opaque, Gum Opaque Modifier

Light curing device	Pre-cure	Final cure
LABOLIGHT LV-III, II / LABOLIGHT DUO	1 min.	—
Halogen / High power LED	20 sec.	—

Note :
 1) The STEPLIGHT SL-I / LABOLIGHT DUO cannot be used to light cure the above materials.
 2) When using a hand held type light curing device*, apply light in all directions for complete polymerization.

Irradiation time for Gum, Gum Modifier, Gum Translucent

Light curing device	Pre-cure	Final cure
LABOLIGHT LV-III, II / LABOLIGHT DUO	30 sec.	3 min.
STEPLIGHT SL-I / LABOLIGHT DUO	10 sec.	—
Halogen / High power LED	20 sec.	1 min.

Note :
 1) The STEPLIGHT SL-I / LABOLIGHT DUO cannot be used for final curing.
 2) When using a hand held type light curing device*, apply light in all directions for complete polymerization.

Depth of cure (using the LABOLIGHT LV-III / LABOLIGHT DUO)

Irradiation time	Pre-cure (30 sec.)	Pre-cure (1 min.)	Final cure (3 min.)
Shades	—	0.2 mm	—
Gum Opaque	—	0.2 mm	—
Gum	1.1 mm	—	2.5 mm
Gum Modifier	0.8 mm	—	1.5 mm
Gum Translucent	3.0 mm	—	5.0 mm

Note :
 The depths of cure for translucent Gum (G20) and Gum Modifier (GM30) are equivalent to that of Gum Translucent.

STORAGE
 Recommended for optimal performance, store in a cool place away from direct sunlight.

SHADES & PACKAGES (GRADIA gum shades)

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 - Syringe of 2.9mL paste - Gum (G24) 1
 - Syringe of 2.4mL gel - Gum Translucent (G14) 1
 - Dispensable palette 1
 - Light protective cover 1
 - Mixing pad No. 22 1
 - Brush No. 7 1
 - Shade guide kit 1
 - Color chart 1

