

## GRADIA™ gum shades

### LIGHT-CURED GUM SHADE COMPOSITE SYSTEM

Use only by a dental professional in the indications for use.

**INDICATIONS FOR USE**  
 Restoration 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.

**PRODUCT DESCRIPTION**  
 GRADIA gum shades is a light-cure material. The particle size of inorganic filler ranges from 0.1-1.7 µm for GUM OPAQUE / GUM OPAQUE MODIFIER, 0.02-2.9 µm for GUM / GUM MODIFIER / GUM TRANSLUCENT. The total amount of inorganic filler is approximately 45 wt% for GUM OPAQUE / GUM OPAQUE MODIFIER / GUM TRANSLUCENT, 67 wt% for GUM.

**COMPOSITION**  
 GUM OPAQUE: GUM OPAQUE MODIFIER, Dimethacrylate, silicon dioxide, multifunctional monomer, initiator, photoinitiator, pigment, stabilizer  
 GUM: Dimethacrylate, silicon dioxide, multifunctional monomer, feldspar, initiator, pigment, stabilizer  
 GUM MODIFIER: GUM TRANSLUCENT, Dimethacrylate, multifunctional monomer, silicon dioxide, feldspar, initiator, pigment, stabilizer  
 GUM FIBER: Pigment

### DIRECTIONS FOR USE

For the following steps (N-1-5) of the procedure, refer to GRADIA instructions for use:

- Preparation of Metal Framework
  - Wrap up framework in usual manner.
  - Use in usual manner.
  - Using a carbide bur, adjust casting in usual manner.
  - Use of Metal Finish
  - Sandblast retention area using 50 to 110 micron aluminum oxide.
  - Use clean water.
- Application of METALPRIMER E / METALPRIMER Z
- Apply one or two coats of METALPRIMER E / METALPRIMER Z to the retention area.

After application of the METALPRIMER E / METALPRIMER Z, immediately apply to apply GRADIA OPAQUE to avoid contamination of the retention area.

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.1 / LABOLIGHT DUO (full mode).

Use the STEPLIGHT SL / LABOLIGHT DUO (step mode) cannot be used for light curing GRADIA FOUNDATION OPAQUE.

Application and Light curing of GRADIA FOUNDATION OPAQUE  
 Apply two thin layers of GRADIA FOUNDATION OPAQUE to the retention area to mask the metal colour. Light cure for 1 minute using the LABOLIGHT LV.1 / LABOLIGHT DUO (full mode).

Use the STEPLIGHT SL / LABOLIGHT DUO (step mode) cannot be used for light curing GRADIA FOUNDATION OPAQUE.

Application and Light curing of GUM OPAQUE (G01)

Apply two thin layers of GUM OPAQUE (G01) to the gum part of the metal framework. Temporarily light cure each layer for 1 minute using LABOLIGHT LV.1 / LABOLIGHT DUO (full mode).

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 (G0M5) to the light cured GUM OPAQUE. Light cure for 1 minute using the LABOLIGHT LV.1 / LABOLIGHT DUO (full mode).

3) The STEPLIGHT SL / LABOLIGHT DUO (step mode) cannot be used for light curing GUM OPAQUE and GUM OPAQUE MODIFIER.

4) Apply GUM (G0) temporarily light cure for 30 seconds using the LABOLIGHT LV.1 / LABOLIGHT DUO (step mode) for 10 seconds using the STEPLIGHT SL / LABOLIGHT DUO (step mode). Finally light cure the whole area using the LABOLIGHT LV.1 / LABOLIGHT DUO (full mode).

Note:

1) If light curing application exceeds the depth of cure mentioned in the chart, apply in layers and light cure respectively (in the LABOLIGHT LV.1 / LABOLIGHT DUO (step mode)).

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 minimize curling shrinkage.

3) If it is desired to reproduce blood vessels in the gum area, incorporate GUM FIBER (F7) in translucent GUM MODIFIER (GM30) or matting MODIFIER (GM35) mix, apply and light cure.

4) When using GUM FIBER, cover with GUM TRANSLUCENT. Light cure only the GUM FIBER.

5) Remove any inhibited layer and Shade adjustment.

Remove any inhibited layer and adjust contour using a carbide bur. Blended zone or cut back.

6) Finish.

7) Polish and buff margin thick than desired and progressively finish using a rubber point or silicone point.

8) 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.1 / LABOLIGHT DUO (full mode)	1 min.	3 min.
LAGOLIGHT / High power LED	20 sec.	30 sec.

Note:

1) The STEPLIGHT SL / LABOLIGHT DUO (step mode) cannot be used to light cure the above material.

2) The STEPLIGHT SL / LABOLIGHT DUO (step mode) cannot be used in all directions for complete polymerization.

### Irradiation time for GUM, GUM MODIFIER, GUM TRANSLUCENT

Light curing device	Pre-cure	Final cure
LABOLIGHT LV.1 / LABOLIGHT DUO (full mode)	1 min.	3 min.
STEPLIGHT SL / LABOLIGHT DUO (step mode)	10 sec.	3 min.
LAGOLIGHT / High power LED	20 sec.	30 sec.

Note:

1) The STEPLIGHT SL / LABOLIGHT DUO (step mode) cannot be used for final curing.

2) Apply a hand held type light curing device, apply light in all directions for complete polymerization.

### Depth of cure (using the LABOLIGHT LV.1 / LABOLIGHT DUO (full mode))

Shades	Irradiation time (30 sec.)	Final cure (3 min.)
GUM OPAQUE	0.2 mm	—
GUM OPAQUE MODIFIER	1.1 mm	2.5 mm
GUM MODIFIER	0.8 mm	1.5 mm
GUM TRANSLUCENT	3.0 mm	5.0 mm

### BYODAC

The depths of cure for translucent GUM (G20) and GUM MODIFIER (GM30) are equivalent to those of GUM TRANSLUCENT.

### SHADES & PACKAGES (GRADIA gum shades)

1 Starter Package	1
Syringe of 2.4 ml. solution - GUM OPAQUE (G01)	1
Syringe of 2.4 ml. paste - GUM OPAQUE (G013)	1
Syringe of 2.9 ml. paste - GUM (G2)	1
Syringe of 2.9 ml. paste - GUM (G24)	1
Disposable palette	1
Syringe of 2.4 ml. paste - GUM TRANSLUCENT (GT4)	1
Light protective cover	1
Mask and No. 22	1
Brush No. 1	1
Brush No. 2	1
Color chart	1
2 Refill Packages	2
a. GUM OPAQUE (G01, G012 or G013)	1
b. GUM (G2)	1
c. GUM OPAQUE MODIFIER (GM05)	1
Syringe of 2.4 ml. solution - GUM TRANSLUCENT (GT4)	1
d. GUM MODIFIER (GM30, GM31, GM32, GM33, GM34, GM35 or GM36)	1
e. GUM TRANSLUCENT (GT4)	1
f. GUM FIBER (F7)	1
g. GUM FIBER (F7)	1

Note: Both of 0.4 g filler.

### THE SHADE COMBINATION CHART of GRADIA gum shades is shown in the manual that is available at <https://www.gc.dental/europe>

### 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. Do not use ultraviolet lights or visible light curing devices that can radiate an invisible light.

4. When light curing material, do not look directly into the light source.

5. When adjusting or polishing composite resin, use a dust collector and wear a dust mask to avoid inhaling dust.

6. The brush can be cleaned with alcohol after use.

7. In all runs, cases the product may cause sensitivity to some persons. If such persons are experienced, discontinue use of the product and refer to a physician.

8. Personal protective equipment (PPE) such as gloves, face masks and eyeglasses should always be worn.

9. Some products referenced in the present IFU may be classified as hazardous according to GHS. Always refer yourself with the safety data sheets available at <https://www.gc.dental/europe>.

10. The IFU is intended for your supplier.

### CLEANING AND DISINFECTING

1. The disinfectant system to avoid cross contamination between patients. This device requires mid-level disinfection. Immediately after use inspect the device for any visible contamination.

2. Do NOT IMMERGE. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level germicide chemical refection according to manufacturer's instructions.

3. For the Summary of Safety and Clinical Performance (SSCP) please see the SHARED database (<https://www.gc.dental/europe>) or contact us at [Regulatory.gcc@gc.dental](mailto:Regulatory.gcc@gc.dental).

4. Unrelated effects: Reporting

There is no evidence of any kind of undesired effect, reaction or similar events experienced by the user of this product, including those not listed in this instruction for use.

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## GRADIA™ gum shades

### ФОТО-ПОЛИМЕРИЗИРАЧА КОМПОЗИТНА СИСТЕМА ОТ ВЕЧНИТЕ ЦВЕТОВЕ

Da se izmalova samo od dentalnog lekara, savazivane instrukcije za upotrebu

**INDIKACIJE ZA UPOTREBU**  
 Restoracija gume tkiva za krunice, kao sto su implant superstrukture i uklonjive metalne ramke.

**KONTRAINDIKACIJE**  
 Izbegavati upotrebu ovog proizvoda kod pacijenata sa poznatom alergijom na metakrilatni monomer ili metakrilatni polimer.

**KONTRAINDIKACIJE**  
 Neprimetno upotrebu ovog proizvoda kod pacijenata sa poznatom alergijom na metakrilatni monomer ili metakrilatni polimer.

**OPISANJE NA PRODUKTU**  
 GRADIA gum shade je svetlopolimerizirajući materijal. Raznovrsna čestica inorganičnog punila varira od 0,01 do 1,7 µm za GUM OPAQUE / GUM OPAQUE MODIFIER, 0,02 do 2,9 µm za GUM / GUM MODIFIER / GUM TRANSLUCENT. Ukupno količina anorganskog punila je približno 45 wt% za GUM OPAQUE / GUM OPAQUE MODIFIER / GUM TRANSLUCENT, 67 wt% za GUM.

**ССТАВ**  
 GUM OPAQUE: GUM OPAQUE MODIFIER, Dimetakrilat, silicij dioksid, multifunkcionalni monomer, inicijator, pigment, stabilizator

GUM: Dimetakrilat, silicij dioksid, multifunkcionalni monomer, feldspar, inicijator, pigment, stabilizator

GUM MODIFIER: GUM TRANSLUCENT, Dimetakrilat, multifunkcionalni monomer, silicij dioksid, feldspar, inicijator, pigment, stabilizator

GUM FIBER: Pigment

### DIREKCIJE ZA UPOTREBU

Za sledece korake (N-1-5) od priprema, polazece instrukcije za upotrebu ovog proizvoda:

1. Priprema metalnog okvira
  - 1) Oklopiti metalni okvir u obliku ramena.
  - 2) Koristiti uobicajni postupak.
  - 3) Koristiti abrazivni materijal za obradu površine metalnog okvira.
  - 4) Koristiti metalni sloj.
  - 5) Koristiti metalni sloj.
  - 6) Koristiti metalni sloj.
2. Aplikacija METALPRIMER E / METALPRIMER Z
3. Aplikacija METALPRIMER E / METALPRIMER Z u retencionskoj oblasti.

Posle aplikacije METALPRIMER E / METALPRIMER Z, odmah primeniti GRADIA OPAQUE da bi se izbeglo kontaminiranje retencionske oblasti.

Aplikacija i svetlopolimerizacija GRADIA FOUNDATION OPAQUE  
 Aplikovati sloj GRADIA FOUNDATION OPAQUE u retencionskoj oblasti da bi se sakrilo metalno bojenje. Svetlopolimerizovati za 1 minut koriscenjem LABOLIGHT LV.1 / LABOLIGHT DUO (punim modom).

Upotrebu STEPLIGHT SL / LABOLIGHT DUO (step mod) ne moze se koristiti za svetlopolimerizaciju GRADIA FOUNDATION OPAQUE.

Aplikacija i svetlopolimerizacija GRADIA FOUNDATION OPAQUE  
 Aplikovati dva tanja sloja GRADIA FOUNDATION OPAQUE u retencionskoj oblasti da bi se sakrilo metalno bojenje. Svetlopolimerizovati za 1 minut koriscenjem LABOLIGHT LV.1 / LABOLIGHT DUO (punim modom).

Upotrebu STEPLIGHT SL / LABOLIGHT DUO (step mod) ne moze se koristiti za svetlopolimerizaciju GRADIA FOUNDATION OPAQUE.

Aplikacija i svetlopolimerizacija GUM OPAQUE (G01)

Aplikovati dva tanja sloja GUM OPAQUE (G01) na gumu delu metalnog okvira. Privremeno svetlopolimerizovati svaki sloj za 1 minut koriscenjem LABOLIGHT LV.1 / LABOLIGHT DUO (step mod) za 10 sekundi koriscenjem STEPLIGHT SL / LABOLIGHT DUO (step mod). Na kraju svetlopolimerizovati celu površinu koriscenjem LABOLIGHT LV.1 / LABOLIGHT DUO (punim modom).

Upotrebu STEPLIGHT SL / LABOLIGHT DUO (step mod) ne moze se koristiti za svetlopolimerizaciju GRADIA FOUNDATION OPAQUE.

Aplikacija i svetlopolimerizacija GUM OPAQUE MODIFIER (GM05)

Aplikovati sloj GUM OPAQUE MODIFIER (GM05) na svetlopolimerizovanu GUM OPAQUE. Svetlopolimerizovati za 1 minut koriscenjem LABOLIGHT LV.1 / LABOLIGHT DUO (punim modom).

Upotrebu STEPLIGHT SL / LABOLIGHT DUO (step mod) ne moze se koristiti za svetlopolimerizaciju GUM OPAQUE MODIFIER (GM05).

Aplikacija i svetlopolimerizacija GUM MODIFIER (GM30)

Aplikovati dva tanja sloja GUM MODIFIER (GM30) na gumu delu metalnog okvira. Privremeno svetlopolimerizovati svaki sloj za 1 minut koriscenjem LABOLIGHT LV.1 / LABOLIGHT DUO (step mod) za 10 sekundi koriscenjem STEPLIGHT SL / LABOLIGHT DUO (step mod). Na kraju svetlopolimerizovati celu površinu koriscenjem LABOLIGHT LV.1 / LABOLIGHT DUO (punim modom).

