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GRADIA™

LIGHT-CURED COMPOSITE FOR CROWN & BRIDGE, INLAY& VENEERS

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

FOR MORE DETAILS READ THE GRADIA USER'S MANUAL.

INDICATIONS FOR USE

- Crown and Bridgework (with metal backing)
- Mosaic restorations: Inlay Crowns, Inlays, Onlays, Laminated Veneers
- Frontal restorations: Juniors

CONTRAINDICATIONS

In any case, ENAMEL Composite may experience sensitivity in some people. If any such reactions are seen, discontinue the use of the product and refer to a physician.

In case of maculation, bruism or denching.

PRODUCT DESCRIPTION

GRADIA is a light-cure material for crown and bridgeworks including occlusal surfaces.

The particle size of inorganic fillers range is 0.01-1.17 µm for FOUNDATION OPAQUE, MARGIN OPAQUE, 0.02-2.9 µm for OPAQUS DENTIN, SHOULDER DENTIN, DENTIN, OPAQUS DENTIN INTENSIVE, ENAMEL, HALO ENAMEL, PEARL ENAMEL, ENAMEL INTENSIVE, TRANSLUCENT, CERVAL, TRANSLUCENT, ENAMEL INTENSIVE, HALO ENAMEL.

The total amount of inorganic fill is approximately 38-46 wt% for FOUNDATION OPAQUE, MARGIN OPAQUE, 74 wt% for OPAQUS DENTIN, SHOULDER DENTIN, DENTIN, OPAQUS DENTIN INTENSIVE, ENAMEL, HALO ENAMEL, PEARL ENAMEL, ENAMEL INTENSIVE, TRANSLUCENT, CERVAL, TRANSLUCENT, ENAMEL INTENSIVE, HALO ENAMEL, 13 wt% for MAMELON STAIN, 47 wt% for FLOWABLE COMPOSITE.

COMPOSITION
FOUNDATION OPAQUE, OPAQUE, MARGIN OPAQUE, Dimethacrylate, silicon dioxide, pigment, initiator, methacrylate polymer, multifunctional monomer, stabilizer
OPAQUE DENTIN, SHOULDER DENTIN, DENTIN, ENAMEL, HALO ENAMEL, PEARL ENAMEL, ENAMEL INTENSIVE, TRANSLUCENT, CERVAL, TRANSLUCENT, ENAMEL INTENSIVE, HALO ENAMEL, Feldspat, dimethacrylate, silicon dioxide, multifunctional monomer, initiator, pigment, stabilizer
TRANSLUCENT, CERVAL, TRANSLUCENT, ENAMEL INTENSIVE, HALO ENAMEL, Dimethacrylate, multifunctional monomer, silicon dioxide, initiator, pigment, stabilizer
FLOWABLE COMPOSITE Dimethacrylate, multifunctional monomer, silicon dioxide, feldspat, initiator, pigment, stabilizer

DIRECTIONS FOR USE

I. Anterior / Posterior Veneer Crown

1. Coat the clean metal framework with METALPRIMER II, Z (GC) and allow to dry.

2. Build up the veneer onto the metal framework in increments in the following order:

a. FOUNDATION OPAQUE, MARGIN OPAQUE, OPAQUE Light cure for 1 minute using LABOUGHT LV.IV. II, DUO (GC).

b. Then SHOULDER DENTIN, OPAQUS DENTIN, DENTIN, MAMELON STAIN, ENAMEL or FLOWABLE COMPOSITE.

c. CERVAL, TRANSLUCENT, ENAMEL INTENSIVE, HALO ENAMEL (on the labial surface).

d. MAMELON STAIN, OPAQUS DENTIN INTENSIVE, HALO ENAMEL (on the lingual surface). Light cure each layer for 30 seconds with LABOUGHT LV.IV. II, DUO (GC) or for 10 seconds with the STEPLIGHT SL-I, LABOUGHT DUO (GC).

Note: FLOWABLE COMPOSITE should be covered by a layer of other pastes such as ENAMEL or ENAMEL INTENSIVE.

3. Coat the veneer surface with GRADIA AIR BARRIER.

4. Final cure for 3 minutes using LABOUGHT LV.IV. II, DUO (GC).

5. Polish with GRADIA DIAPOLISHER on a felt wheel, etc.

II. Anterior or Posterior Jacket Crown

1. a. Harden the stone both surface with GRADIA DIE-HARDNER.

b. Apply a layer of paraffin wax as die spacer, if required.

c. Coat the die surface with GRADIA SEPARATOR.

2. Build up the crown onto the stone die in increments in the following order:

a. OPAQUE (on the labial surface), MARGIN OPAQUE (on the lingual surface). Light cure each layer for 1 minute with LABOUGHT LV.IV. II, DUO (GC).

b. Then SHOULDER DENTIN, OPAQUS DENTIN, DENTIN, MAMELON STAIN, ENAMEL or FLOWABLE COMPOSITE.

c. CERVAL, TRANSLUCENT, ENAMEL INTENSIVE, HALO ENAMEL (on the labial surface).

d. MAMELON STAIN, OPAQUS DENTIN INTENSIVE, HALO ENAMEL (on the lingual surface). Light cure each layer for 30 seconds with LABOUGHT LV.IV. II, DUO (GC) or for 10 seconds the STEPLIGHT SL-I, LABOUGHT DUO (GC).

Note: FLOWABLE COMPOSITE should be covered by a layer of other pastes such as ENAMEL or ENAMEL INTENSIVE.

3. Coat the veneer surface with GRADIA AIR BARRIER.

4. Final cure for 3 minutes using LABOUGHT LV.IV. II, DUO (GC).

5. Polish with GRADIA DIAPOLISHER on a felt wheel, etc.

III. Posterior Inlay

1. a. Harden the stone cavity with GRADIA DIE-HARDNER.

b. Block out undercuts with wax.

c. Apply a layer of paraffin wax as die spacer, if required.

d. Coat the die surface with GRADIA SEPARATOR.

2. Build up the crown onto the stone die in increments in the following order:

a. FOUNDATION OPAQUE, MARGIN OPAQUE, OPAQUE Light cure each layer for 30 seconds with LABOUGHT LV.IV. II, DUO (GC) or for 10 seconds with STEPLIGHT SL-I, LABOUGHT DUO (GC).

b. Then SHOULDER DENTIN, OPAQUS DENTIN, DENTIN, MAMELON STAIN, ENAMEL or FLOWABLE COMPOSITE.

c. CERVAL, TRANSLUCENT, ENAMEL INTENSIVE, HALO ENAMEL (on the labial surface).

d. MAMELON STAIN, OPAQUS DENTIN INTENSIVE, HALO ENAMEL (on the lingual surface). Light cure each layer for 30 seconds with LABOUGHT LV.IV. II, DUO (GC) or for 10 seconds the STEPLIGHT SL-I, LABOUGHT DUO (GC).

Note: FLOWABLE COMPOSITE should be covered by a layer of other pastes such as ENAMEL or ENAMEL INTENSIVE.

3. Coat the crown surface with GRADIA AIR BARRIER.

4. Final cure for 3 minutes using LABOUGHT LV.IV. II, DUO (GC).

5. Polish with GRADIA DIAPOLISHER on a felt wheel, etc.

IV. Composite Primer

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

2. GRADIA SEPARATOR, GRADIA DIE HARDNER and METALPRIMER II, Z (GC) should be used in a clean, dry and vapour. Do not use near open flame. Keep away from sources of heat. Keep away from children.

3. When adjusting or polishing the veneer surface, use a dust collector and wear a dust mask to avoid inhaling dust.

4. In case of contact with eyes, immediately wash the eye with copious amounts of water and seek medical attention.

5. Dispose of all waste according to local regulations.

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STORAGE

Recommended for optimal performance, store in a cool and dark place (4-25°C / 39-77°F).

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

FOR A SUMMARY OF THE CLINICAL PERFORMANCE (SSCP) PLEASE SEE EUADAMED DATABASE (<https://ec.europa.eu/ortho/euadamed>) OR CONTACT US AT Regulatory.ge@gc.dental/europe

UNDESIRABLE EFFECTS

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CERVAL TRANSLUCENT

Dimetilakrilat, silicium dioksid, pigment, inihator, metakrilat, multifunkcionalni monomer, stabilizator

3. Na povrch krunice naneste GRADIA AIR BARRIER.

4. Konecny vyzivaci postup provadte 3 minuty pomocí LABOUGHT LV.IV. II, DUO (GC).

5. Vyleštite pomocí GRADIA DIAPOLISHER na pleteném kotkovicu atd.

III. Inlay v distálním úseku

1. a. Sadržovú vrstvu zpevnite pomocí GRADIA DIE-HARDNER.

b. Vloženou výplňkou potesťte v mieste c. V prípade potreby naneste vrstvu parafínového vosku ako medzivrstvu.

2. Na sdržovú masu naneste GRADIA SEPARATOR.

3. Na povrch krunice naneste GRADIA AIR BARRIER.

4. Konecny vyzivaci postup provadte 3 minuty pomocí LABOUGHT LV.IV. II, DUO (GC).

5. Vyleštite pomocí GRADIA DIAPOLISHER na pleteném kotkovicu atd.

IV. Composite Primer

1. Osobné ochranné pomôcky použite podľa potreby.

2. GRADIA SEPARATOR, GRADIA DIE HARDNER a METALPRIMER II, Z (GC) by sa mali používať v čistom, suchom prostredí. Neodporúčame ich používať v blízkosti otvoreného ohňa. Uchovávajte mimo zdrojov tepla. Držte dieťa od detských súprôb. Dávajte pozor na detskú hru.

3. Pri upravovaní alebo leštení povrchu použite ochranné pomôcky.

4. Pri kontakte s očami okamžite vypláchnite očami veľkým množstvom vody a vyhľadajte lekárske pomôcky.

5. Pri kontakte s tvárou okamžite vypláchnite tvárou veľkým množstvom vody a vyhľadajte lekárske pomôcky.

6. Všetky odpadky skladujte v súlade s miestnymi predpismi.

UKLADNANIE

Pro optimální výsledky, skladujte na chladném a tmavém místě (4-25°C / 39-77°F).

POZOROVANIE

1) Osobní ochranné pomůcky jako rukavice, roušku a ochranný kryt.

2) GRADIA SEPARATOR, GRADIA DIE HARDNER a METALPRIMER II, Z (GC) by se měly používat v čistém, suchém prostředí. Neodporujeme je používat v blízkosti otevřeného ohně. Uchovávejte mimo zdroje tepla. Držte dítě od dětských souprav. Dávejte pozor na dětskou hru.

3) Při upravování nebo leštění povrchu použijte ochranné pomůcky.

4) Při kontaktu s očima okamžitě vypláchněte očima velkým množstvím vody a vyhledejte lékařskou pomoc.

5) Při kontaktu s tváří okamžitě vypláchněte tváří velkým množstvím vody a vyhledejte lékařskou pomoc.

6) Všechny odpady skladujte v souladu s místními předpisy.

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