

Prior to use, carefully read the instructions for use.

EN

**OPTIGLAZE™**  
NANO FILLED LIGHT CURED PROTECTIVE COATING FOR COMPOSITE AND ACRYLIC INDIRECT RESTORATIONS

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

**RECOMMENDED INDICATIONS**  
1. Coating of indirect composite surfaces (fissures and interproximal areas)  
2. Coating of denture base surfaces  
3. Coating of provisional materials

**CONTRAINDICATIONS**  
Avoid the use of this product in patients with known allergies to acrylic or methacrylate monomer.

**PRECAUTIONS**  
1. It is not recommended to use OPTIGLAZE on high stress bearing areas (occlusal surfaces).  
2. The use of OPTIGLAZE does not replace the mechanical polishing of aesthetic indirect composite restorations such as GRADIA.

**DIRECTIONS FOR USE**

Preparation:  
After contouring the resin surface, finish with carbide bur or coarse silicon point. Clean the surface with a steam cleaner or ultrasonic cleaner and then dry. If surface still contains oil residue, the surface can be further cleaned with ethanol (alcohol).

**NOTE:**  
1) OPTIGLAZE does not adhere to a polished surface. Make sure surfaces to be coated are rough.  
2) The air-inhibited layer of the resin surface to be coated should be removed before applying OPTIGLAZE as it may inhibit the proper curing of OPTIGLAZE.

3) The use of ethanol (alcohol) on acrylic resin may cause micro-cracks. A mild detergent can be used to clean the acrylic resin.

**Application:**  
1. Dispense a few drops into a dispensing dish. Replace bottle cap immediately after dispensing.  
2. IMMEDIATELY apply (within 1 minute after dispensing) to the surface with a brush. DO NOT AIR BLOW.

**Light Curing:** Light cure with a suitable light curing device.

LABOLIGHT DUO 90 sec.

LABOLIGHT LV-III, II 3 min.

STEPLIGHT SL-I Distance from light source <3 cm 10 sec.

STEPLIGHT SL-I Distance from light source >3 cm 20 sec.

Halogen Light 40 sec.

LED Light (with light source having wavelength lower than 430 nm) 40 sec.

**NOTES:**

1) If surface is hazy, repeat light curing.  
2) If necessary, re-cure the product a half-turn or turn-over and light again to ensure all surfaces are completely cured.

3) Additional build-up cannot be performed on surfaces coated with OPTIGLAZE. Remove the coated layer with a bur and then build-up.

4) OPTIGLAZE cannot be cured by a conventional LED light curing device (e.g. Lumen LED).

5) When using other manufacturers' light curing devices, use final curing mode. Refer to the respective manufacturers' instructions for use.

**STORAGE:** Recommended for optimal performance, store at temperature of 4-25°C (39.2-77.0°F).

**PACKAGE:** OPTIGLAZE 15 mL (1)

**CAUTION:**

1. OPTIGLAZE is flammable. Do not use near open flame. Keep away from sources of ignition. Do not store large quantities in one area.

2. OPTIGLAZE is volatile. Use in a well ventilated area. Replace cap immediately after dispensing.

3. In contact with eyes, flush immediately with water and seek medical attention.

4. In case of contact with skin, immediately remove with a sponge or cotton pellet. Flush with water.

5. Wear protective gloves. In particular, avoid contact of uncured OPTIGLAZE with skin.

6. Avoid contact with clothing.

7. Avoid inhalation or ingestion of material.

8. Do not mix with other products.

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

10. In rare cases the product may cause sensitivity to some people. If any such reactions are experienced, discontinue the use of the product and refer to a physician.

Some products referenced in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the data sheet available at:

<http://www.gc-europe.com>

They can also be obtained from your supplier.

**CLEANING AND DISINFECTING:**

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

**Undesired effects- Reporting:**

If you become aware of any kind of undesired effect, reaction or similar events experienced with the use of the 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](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en) as well as to our internal vigilance system: [vigilance@gc.dental](mailto:vigilance@gc.dental)

In this way will contribute to improve the safety of this product.

Last revised: 06/2019

**GC**

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Pred upotreba, внимателно прочете инструкции за употреба.

BG

Před použitím si pečlivě přečtěte návod k použití.

CS

Prije uporabe pažljivo prečitajte návod k uporabi.

HR

Hasonló eljött az útmutatót olvassa el a felhasználó!

HU

Przed użyciem przeczytaj uwagę instrukcję stosowania.

PL

Inainte de utilizare, citiți cu atenție instrucțiunile de folosire.

RO

Vнимательно прочтите инструкции перед применением.

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