

## OPTIGLAZE™ color

LIGHT-CURED CHARACTERIZATION MATERIAL

Use only by a dental professional in the recommended indications.

### RECOMMENDED INDICATIONS

1. Characterization of direct & indirect composite restorations, acrylic denture base and acrylic denture relines. 2. For obtaining surface smoothness and wear resistance of restorations made of composite resin, acrylic denture base and artificial acrylic teeth. 3. For polishing on glass ionomer cements. Not intended for characterization of natural teeth.

### CONTRAINDICATIONS

Avoid use of this product in patients with known allergies to acrylate / methacrylate monomers or acrylate / methacrylate polymers.

### DIRECTIONS FOR USE

Surface characterization: 1) After contouring the resin surface, finish with a carbide bur or coarse silicone point. The oxygen inhibition layer must be removed as it inhibits the polymerization of OPTIGLAZE color. Laboratory use: Sandblast with 25-50µm alumina (0.15MPa/1.5bar), clean and dry. NOTE: 1) If surface still contains oil residue, the surface can be cleaned further with ethanol (alcohol). The use of ethanol (alcohol) on acrylic resin may cause micro cracks. A mild detergent can be used to clean the acrylic resin. 2) When applying OPTIGLAZE color on hybrid ceramic blocks such as Clear Clear HV, use CERAMIC PRIMER II. 2) Shake the bottle of OPTIGLAZE color well. Dispense a few drops in a dispensing dish. Dilute by adding color to the desired shade. Apply a thin layer of dentin primer or primer. Do not air blow. 3) Light cure with a suitable light curing device. (See table 1) Place the light curing device as close as possible to the surface. Laboratory use: Set a 2cm platform in the curing device and place the prosthesis on the surface facing the light. Reverse the prosthesis and repeat the curing. Repeat the light curing to fully cure the undercut or area in shadow.

Internal characterization: 1) Build up the dentin layer with composite and light cure. Follow the instructions of your composite system.

Do not remove the oxygen inhibition layer. Apply OPTIGLAZE color on the oxygen inhibition layer. If the oxygen inhibition layer is removed, treat the surface with CERAMIC PRIMER II (blow dry) and COMPOSITE PRIMER (light cure) before applying OPTIGLAZE color. 1) Shake the bottle of OPTIGLAZE color well. Dispense a few drops in a disposable dispensing dish. Apply a thin layer of OPTIGLAZE color of choice to the dentin surface with an instrument or brush (e.g. the convex and concave of dentin margin or incisal area). Mix multiple colors to obtain the desired shade if needed. Do not air blow. 2) Light cure with a suitable light curing device. (See table 1) 4) Continue building up with enamel shade of the oxygen inhibition layer. Follow the instructions of your composite system. 5) Apply the finish with CERAMIC CLEAR or CLEAR HV shade to the surface.

Repair of restoration (if the gloss is lost): 1) Roughen the surface of restoration using a carbide bur and paper cone 2) Cleanse and finish with a steam cleaner or ultrasonic cleaner and then dry with free air. NOTE: 1) Resin is contaminated by oil residue, the surface can be cleaned further with ethanol (alcohol). The use of ethanol (alcohol) on acrylic resin may cause micro cracks. A mild detergent can be used to clean the acrylic resin. 2) Apply the finish with CERAMIC CLEAR or CLEAR HV shade to the surface. Do not air blow. 3) Light cure with a suitable light curing device. (See table 1)

Table 1: Light Cure Time	90 sec.
GC LABLIGHT DUO	90 sec.
GC LABLIGHT LV-III	5 min.
GC STEPLIGHT SL-I	Distance from light source <3cm 10 sec.
	Distance from light source >3cm 20 sec.
Halogen Light	
Plasma Arc	4 sec.
LED Light (with light source having wavelength lower than 430nm)	8 sec.
Table 2: Depth of Cure	
Orange, Yellow, Red/brown, Red	0.07 mm
A Plus, B Plus, C Plus, White, Ivory White, Pink Orange, Pink, Clear, Lavender, Grey, Blue	0.15 mm
Clear, Clear HV	0.5 mm

**STORAGE**  
Recommended for optimal performance, store at room temperature of 4-25°C (39-77°F).

**PACKAGE:**  
Complete set:  
A Plus, B Plus, C Plus, White, Ivory White, Pink Orange, Pink, Clear, Lavender, Grey, Blue  
Clear HV, Clear HV 5ml, jednorazová dávková miska, plochá štětka, křída

**CAUTION**  
1. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn. 2. Particular avoid contact of uncured material with skin. 3. Avoid getting material on clothing. 4. OPTIGLAZE color is highly flammable liquid and vapor. DO not use near open flame. Keep away from source of ignition. 5. OPTIGLAZE color is volatile and may cause respiratory irritation. Use in a well-ventilated space. Replace cap immediately after dispensing. 6. It is not recommended to use OPTIGLAZE color on high pressure bearing area. 7. Avoid contact with eyes, flush immediately with water and seek medical attention. 8. In case of contact with skin, immediately remove with a sponge or cotton ball. 9. The oxygen inhibited layer of the resin surface to be coated should be removed before applying OPTIGLAZE color as it may hinder the proper curing of the product. 10. Dispense a few drops of OPTIGLAZE color into a disposable dispensing dish. Do not dispense directly from the syringe. 11. Do not use OPTIGLAZE color on volatile solvent. 12. Store locked up. 13. Dispose all waste according to local regulation. 14. Do not use 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.

**CLEANING AND DISINFECTING**  
1. Use disinfectant to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. 2. Rinse essential to avoid cross-contamination. 3. Do not IMMERGE. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level disinfectant. 4. Rinse essential to avoid cross-contamination. 5. Follow regional/national guidelines.

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13. В связи с данным продуктом могут да предвзятая чувствительность у некоторых людей. При таких реакциях, прекратите использование на продукта и сообщите об этом.

**ПОЧИНЕНИЕ И ДЕЗИНФИКАЦИЯ**  
ДОЗАРКТИВ СИСТЕМЫ ЗА МНОГОКРАТНУЮ УПОТРЕБУ: за да се избегне кръстосано замърсяване между пациентите, устройството изисква средно ниво на дезинфекция преди и след употреба. Не иммерсирайте устройството, веднага след употреба инспектирайте устройството и етикета за влошаване на състоянието. Извършете почистване и етикетта, ако е уредено.

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FOTOPOLIMERIZIRAJIČNI MATERIAL ZA PRIDAVANJE NA KARAKTERISTIKI

Uporaba samo od dentalni specialisti sporod preporočanih indikacij.

### PREPORUČANE INDIKACIJE

1. Karakteriziranje na direktni in neposredni kompozitni vrstnoobnavljanje, plastmasova osnova na protezi in plastmasovi zubi. 2. Za poliranje na staklenih ionomernih cementih. Ni namenjeno za karakteriziranje naravnih zob.

### CONTRAINDICACIJE

Uporaba tega izdelka pri pacientih s poznanimi alergijami na akrilat / metakrilatne monomere ali akrilat / metakrilatne polimere.

### NAVODI ZA UPOTREBA

1) Po vytváření povrchu z pryskydky, dokončete kartádkovým bruskem nebo trubicou silikonovou. Kvalitně imobilizovanou vrstvu musí být odstráněna, protože negativně ovlivňuje polymeraci OPTIGLAZE color. Laboratorní použití: Pískujte osedlem třílným 25-50 µm (0.15MPa/1.5bar), očistěte a osušte. POZNÁMKA: 1) Jestliže povrch stále obsahuje zbytky oleje, lze ho ještě očistit etanolem (alkoholem). Použití etanolu (alkoholu) na akrylové pryskyčce způsobí mikrotrhliny. K čišění akrylové pryskyčce může být použito jemné šetrné čističké prostředky. 2) Při aplikaci OPTIGLAZE color na hybridní bloky s keramickým povrchem jako jsou CERAMART, použijte na ošetření povrchu CERAMIC PRIMER II. 2) Shake the bottle of OPTIGLAZE color well. Dispense a few drops in a dispensing dish. Dilute by adding color to the desired shade. Apply a thin layer of dentin primer or primer. Do not air blow. 3) Light cure with a suitable light curing device. (See table 1) Place the light curing device as close as possible to the surface. Laboratory use: Set a 2cm platform in the curing device and place the prosthesis on the surface facing the light. Reverse the prosthesis and repeat the light curing to fully cure the undercut or area in shadow.

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SVETLENI THUNOVSKI MATERIAL PRO ZVYRANÉHO CHARAKTERISTIKY

Použití pouze ve stomatologické praxi s doporučenými indikacemi.

### DOPORUČENÉ INDIKACE

1. Charakteristika přímých a nepřímých kompozitních výplní, akrylových bázových a akrylových denturních zubů. 2. Za polštění na skleněných ionomerních cementech. Ni je namenjeno za karakteriziranje naravnih zob.

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Uporaba tega izdelka pri pacientih s poznanimi alergijami na akrilat / metakrilatne monomere ali akrilat / metakrilatne polimere.

### NAVODI ZA UPOTREBU

1) Po vytváření povrchu z pryskydky, dokončete kartádkovým bruskem nebo trubicou silikonovou gumou. Kvalitně imobilizovanou vrstvu musí být odstráněna, protože negativně ovlivňuje polymeraci OPTIGLAZE color. Laboratorní použití: Pískujte osedlem třílným 25-50 µm (0.15MPa/1.5bar), očistěte a osušte. POZNÁMKA: 1) Jestliže povrch stále obsahuje zbytky oleje, lze ho ještě očistit etanolem (alkoholem). Použití etanolu (alkoholu) na akrylové pryskyčce způsobí mikrotrhliny. K čišění akrylové pryskyčce může být použito jemné šetrné čističké prostředky. 2) Při aplikaci OPTIGLAZE color na hybridní bloky s keramickým povrchem jako jsou CERAMART, použijte na ošetření povrchu CERAMIC PRIMER II. 2) Shake the bottle of OPTIGLAZE color well. Dispense a few drops in a dispensing dish. Dilute by adding color to the desired shade. Apply a thin layer of dentin primer or primer. Do not air blow. 3) Light cure with a suitable light curing device. (See table 1) Place the light curing device as close as possible to the surface. Laboratory use: Set a 2cm platform in the curing device and place the prosthesis on the surface facing the light. Reverse the prosthesis and repeat the light curing to fully cure the undercut or area in shadow.

Internal characterization: 1) Build up the dentin layer with composite and light cure. Follow the instructions of your composite system.

Do not remove the oxygen inhibition layer. Apply OPTIGLAZE color on the oxygen inhibition layer. If the oxygen inhibition layer is removed, treat the surface with CERAMIC PRIMER II (blow dry) and COMPOSITE PRIMER (light cure) before applying OPTIGLAZE color. 1) Shake the bottle of OPTIGLAZE color well. Dispense a few drops in a disposable dispensing dish. Apply a thin layer of OPTIGLAZE color of choice to the dentin surface with an instrument or brush (e.g. the convex and concave of dentin margin or incisal area). Mix multiple colors to obtain the desired shade if needed. Do not air blow. 2) Light cure with a suitable light curing device. (See table 1) 4) Continue building up with enamel shade of the oxygen inhibition layer. Follow the instructions of your composite system. 5) Apply the finish with CERAMIC CLEAR or CLEAR HV shade to the surface.

Repair of restoration (if the gloss is lost): 1) Roughen the surface of restoration using a carbide bur and paper cone 2) Cleanse and finish with a steam cleaner or ultrasonic cleaner and then dry with free air. NOTE: 1) Resin is contaminated by oil residue, the surface can be cleaned further with ethanol (alcohol). The use of ethanol (alcohol) on acrylic resin may cause micro cracks. A mild detergent can be used to clean the acrylic resin. 2) Apply the finish with CERAMIC CLEAR or CLEAR HV shade to the surface. Do not air blow. 3) Light cure with a suitable light curing device. (See table 1)

Table 1: Light Cure Time	90 sec.
GC LABLIGHT DUO	90 sec.
GC LABLIGHT LV-III	5 min.
GC STEPLIGHT SL-I	Distance from light source <3cm 10 sec.
	Distance from light source >3cm 20 sec.
Halogenová lampy	
Plazma oblaka	4 sek.
LED světlo (s světelným zdrojem s vlnovou délkou nižší než 430 nm)	8 sek.
Table 2: Hloubka vztvrdnutí	
Orange, Yellow, Red/brown, Red	0.07 mm
A Plus, B Plus, C Plus, White, Ivory White, Pink Orange, Pink, Clear, Lavender, Grey, Blue	0.15 mm
Clear, Clear HV	0.5 mm

**STORAGE**  
Recommended for optimal performance, store at room temperature of 4-25°C (39-77°F).

**PACKAGE:**  
Complete set:  
A Plus, B Plus, C Plus, White, Ivory White, Pink Orange, Pink, Clear, Lavender, Grey, Blue  
Clear HV, Clear HV 5ml, jednorazová dávková miska, plochá štětka, křída

**CAUTION**  
1. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn. 2. Particular avoid contact of uncured material with skin. 3. Avoid getting material on clothing. 4. OPTIGLAZE color is highly flammable liquid and vapor. DO not use near open flame. Keep away from source of ignition. 5. OPTIGLAZE color is volatile and may cause respiratory irritation. Use in a well-ventilated space. Replace cap immediately after dispensing. 6. It is not recommended to use OPTIGLAZE color on high pressure bearing area. 7. Avoid contact with eyes, flush immediately with water and seek medical attention. 8. In case of contact with skin, immediately remove with a sponge or cotton ball. 9. The oxygen inhibited layer of the resin surface to be coated should be removed before applying OPTIGLAZE color as it may hinder the proper curing of the product. 10. Dispense a few drops of OPTIGLAZE color into a disposable dispensing dish. Do not dispense directly from the syringe. 11. Do not use OPTIGLAZE color on volatile solvent. 12. Store locked up. 13. Dispose all waste according to local regulation. 14. Do not use 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.

**CLEANING AND DISINFECTING**  
1. Use disinfectant to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. 2. Rinse essential to avoid cross-contamination. 3. Do not IMMERGE. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level disinfectant. 4. Rinse essential to avoid cross-contamination. 5. Follow regional/national guidelines.

Some products referred to in the present IVD may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheets available at: <http://www.geplore.com>

They can also be obtained from your supplier.

Undesired effects - Reporting: If you become aware of any kind of undesired effect, reaction or similar events during the 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 according to the following link.

[https://ec.europa.eu/eur/whistleblowers/medical-devices/contacts\\_en](https://ec.europa.eu/eur/whistleblowers/medical-devices/contacts_en) or via online system vigilance@geplore.com  
13. В связи с данным продуктом могут да предвзятая чувствительность у некоторых людей. При таких реакциях, прекратите использование на продукта и сообщите об этом.

**ПОЧИНЕНИЕ И ДЕЗИНФИКАЦИЯ**  
ДОЗАРКТИВ СИСТЕМЫ ЗА МНОГОКРАТНУЮ УПОТРЕБУ: за да се избегне кръстосано замърсяване между пациентите, устройството изисква средно ниво на дезинфекция преди и след употреба. Не иммерсирайте устройството, веднага след употреба инспектирайте устройството и етикета за влошаване на състоянието. Извършете почистване и етикетта, ако е уредено.

13. В связи с данным продуктом могут да предвзятая чувствительность у некоторых людей. При таких реакциях, прекратите использование на продукта и сообщите об этом.

Некои продукти, споменати в настоящите инструкции, могат да бъдат определени като опасни съгласно GHS. Винаги се запознавайте с информационните данни за безопасност GHS. Винаги се запознавайте с информационните данни за безопасност GHS. Винаги се запознавайте с информационните данни за безопасност GHS.

They can also be obtained from your supplier.

Undesired effects - Reporting: If you become aware of any kind of undesired effect, reaction or similar events during the 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 according to the following link.

[https://ec.europa.eu/eur/whistleblowers/medical-devices/contacts\\_en](https://ec.europa.eu/eur/whistleblowers/medical-devices/contacts_en) or via online system vigilance@geplore.com  
13. В связи с данным продуктом могут да предвзятая чувствительность у некоторых людей. При таких реакциях, прекратите использование на продукта и сообщите об этом.

**ПОЧИНЕНИЕ И ДЕЗИНФИКАЦИЯ**  
ДОЗАРКТИВ СИСТЕМЫ ЗА МНОГОКРАТНУЮ УПОТРЕБУ: за да се избегне кръстосано замърсяване между пациентите, устройството изисква средно ниво на дезинфекция преди и след употреба. Не иммерсирайте устройството, веднага след употреба инспектирайте устройството и етикета за влошаване на състоянието. Извършете почистване и етикетта, ако е уредено.

13. В связи с данным продуктом могут да предвзятая чувствительность у некоторых людей. При таких реакциях, прекратите использование на продукта и сообщите об этом.

Некои продукти, споменати в настоящите инструкции, могат да бъдат определени като опасни съгласно GHS. Винаги се запознавайте с информационните данни за безопасност GHS. Винаги се запознавайте с информационните данни за безопасност GHS. Винаги се запознавайте с информационните данни за безопасност GHS.

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

DE  
Vor der Benutzung bitte die Gebrauchsanweisung gründlich lesen!

FR  
Avant toute utilisation, lire attentivement les instructions d'emploi.

IT  
Leggere attentamente le istruzioni prima dell'uso.

ES  
Antes de usar, leer detenidamente las instrucciones de uso.

NL  
Lees voor gebruik zorgvuldig de gebruiksaanwijzing.

## OPTIGLAZE™ color

LIGHT-CURED CHARACTERIZATION MATERIAL

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

### RECOMMENDED INDICATIONS

- Characterization of direct composite restorations, acrylic denture base and artificial acrylic teeth.
- For obtaining surface smoothness and wear resistance of restorations made of composite resin, acrylic denture base and artificial acrylic teeth.

Note:  
Not intended for characterization of natural teeth.

### CONTRAINDICATIONS

Avoid use of this product in patients with known allergies to acrylate / methacrylate monomers or acrylate / methacrylate polymers.

### DIRECTIONS FOR USE

Surface characterization  
1. After contouring the resin surface, finish with a carbide bur or coarse silicone point. The oxygen inhibition layer must be removed as it inhibits the polymerization of OPTIGLAZE color.  
Laboratory use:  
Sandblast with 25-50 µm alumina (0.15 MPa/1.5 bar), clean and dry.

- If surface still contains oil residue, the surface can be cleaned further with ethanol (alcohol). The use of ethanol (alcohol) on acrylic resin may cause micro cracks. A mild detergent can be used to clean the acrylic resin.
- When applying OPTIGLAZE color on hybrid ceramic blocks such as CERASMART, treat the surface using CERAMIC PRIMER II.
- Shake the bottle of OPTIGLAZE color well. Dispense a few drops in a dispensing dish. Dilute by adding CLEAR to the desired shade. Apply a thin layer to the resin surface using the brush provided. Do not air blow.
- Light cure with a suitable light curing device. (See table 1) Place the light tip as close as possible to the surface.  
Laboratory use:  
Set a 2 cm platform in the curing device and place the prosthesis on it with the coated surface facing the light. Reverse the prosthesis and repeat the light curing to fully cure the undercut or area in shadow.

### Internal characterization

- Build up the dentin layer with composite and light cure. Follow the instructions of your composite system.  
Note:  
Do not remove the oxygen inhibition layer. Apply OPTIGLAZE color on the oxygen inhibition layer. If the oxygen inhibition layer is removed, treat the surface with CERAMIC PRIMER II (flow dry) and COMPOSITE PRIMER (light cure) before applying OPTIGLAZE color.
- Shake the bottle of OPTIGLAZE color well. Dispense a few drops in a disposable dispensing dish. Apply a thin layer of OPTIGLAZE color of choice to the dentin surface with an instrument or brush (e.g. the convex and concave of dentin mamon or incisal areas). Mix multiple colors to obtain the desired shade if needed. Do not air blow.
- Light cure with a suitable light curing device. (See table 1)
- Continue building up with enamel shade on the oxygen inhibition layer. Follow the instructions of your composite system.
- Finish and polish using standard technique or apply OPTIGLAZE color CLEAR or CLEAR HV on the entire surface.

### Repair of restoration (e.g. when the glass is lost)

- Roughen the surface of restoration using a carbide bur and paper the face.
- Clean the surface with a steam cleaner or ultrasonic cleaner and then dry with oil free air.

Note:  
If surface is contaminated by oil residue, the surface can be cleaned further with ethanol (alcohol). The use of ethanol (alcohol) on acrylic resin may cause micro cracks. A mild detergent can be used to clean the acrylic resin.

- Apply OPTIGLAZE color CLEAR or CLEAR HV shade to the surface. Do not air blow.
- Light cure with a suitable light curing device. (See table 1)

Table 1: Light Curing Time	
GC LABOLIGHT DUO	90 sec.
GC LABOLIGHT LV-III II	5 min.
GC STEPLIGHT SL-I	Distance from light source <3 cm 10 sec. Distance from light source >3 cm 20 sec.
Halogen Light	40 sec.
Plasma Arc	8 sec.
LED Light (with light source having wavelength lower than 430 nm)	40 sec.
Table 2: Depth of Cure	
Orange, Yellow, Red/Brown, Red	0.07 mm
A Plus, B Plus, C Plus, White, Ivory White, Pink Orange, Pink, Olive, Lavender, Grey, Blue	0.15 mm
Clear, Clear HV	0.5 mm

**STORAGE**  
Recommended for optimal performance, store at room temperature of (4-25°C) (39-77.0°F).

**PACKAGE:**  
Complete set:  
A Plus 2.6 mL, B Plus 2.6 mL, C Plus 2.6 mL, White 2.6 mL, Ivory White 2.6 mL, Yellow 2.6 mL, Orange 2.6 mL, Pink Orange 2.6 mL, Pink 2.6 mL, Red Brown 2.6 mL, Olive 2.6 mL, Lavender 2.6 mL, Grey 2.6 mL, Blue 2.6 mL, Red 2.6 mL, Clear 5 mL, Clear HV 5 mL, Disposable Dispensing Dish, Flat Brush, Round Brush.

- Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.
- In particular avoid contact of material with skin.
- Avoid getting material on clothing.
- OPTIGLAZE color is highly flammable liquid and vapor. Do not use near open flame. Keep away from sources of ignition.
- OPTIGLAZE color is volatile and may cause respiratory irritation. Use in a well ventilated space. Replace cap immediately after dispensing.
- It is not recommended to use OPTIGLAZE color on high pressure bearing area.
- In case of contact with skin, flush immediately with water and seek medical attention.
- In case of contact with eyes, immediately remove with a sponge or cotton pellet. Flush with water.
- The oxygen inhibited layer of the resin surface to be coated should not be removed before applying OPTIGLAZE color as it may hinder the proper curing of OPTIGLAZE color.
- Dispense a few drops of OPTIGLAZE color into a disposable dispensing dish immediately before applying as the material contains a volatile solvent.
- Store locked up.
- Dispose all waste according to local regulation.
- 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.

**CLEANING AND DISINFECTING:**  
MULTI-USE 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 IMMERGE. 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.

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

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](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 you will contribute to improve the safety of this product.

Last revised: 07/2019



Rx Only

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## OPTIGLAZE™ color

LICHTHÄRTENDES CHARAKTERISIERUNGSMATERIAL

Die Anwendung darf bei empfohlenen Indikationen nur durch einen Zahnarzt/Zahntechniker erfolgen.

### EMPFOHLENE INDIKATIONEN

- Charakterisierung von direkt & indirekten Kompositrestaurationen, Kunststoff-Prothesen und Kunststoffzähnen.
- Zur Gewinnung von Oberflächenglätte und Abriebfestigkeit von Kompositrestaurationen, Kunststoff-Prothesen und Kunststoffzähnen.

HINWEIS:  
Es ist nicht für die Charakterisierung von natürlichen Zähnen.

### KONTRAINDIKATIONEN

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

### GEBRAUCHSANWEISUNG

Oberflächencharakterisierung  
Nach der Konturierung der Kompositoberfläche schließen Sie die Bearbeitung von Acrylaten oder einem groben Silikonpolierab. Die Sauerstoff-Inhibitionsschicht muss entfernt werden, da sie die Polymerisation von OPTIGLAZE

- Wenn die Oberfläche noch Ölrückstände aufweist, kann sie mit Ethanol (Alkohol) gereinigt werden. Die Verwendung von Ethanol (Alkohol) auf Acrylaten kann Mikrorisse verursachen.
- Zur Reinigung des Acrylates kann ein mildes Reinigungsmittel verwendet werden.
- Wenn OPTIGLAZE color auf Hybrid-Keramik-Blöcke wie CERASMART aufgetragen werden, behandeln Sie die Oberfläche mit CERAMIC PRIMER II (flow dry) und COMPOSITE PRIMER II (light cure) bevor Sie OPTIGLAZE color auftragen.
- Schütteln Sie die Flasche OPTIGLAZE color gut. Bringen Sie ein paar Tropfen in einen Amnischbehälter. Verdünnen Sie, indem Sie CLEAR zum gewünschten Farbton hinzugeben. Tragen Sie mit dem beigefügten Pinsel eine dünne Schicht auf die Oberfläche auf. Trocknen Sie die Schicht nicht mit Luft.
- Härten Sie die Schicht mit einem geeigneten Licht härtegerät. (Siehe Tabelle 1.) Bringen Sie die Spitze des Licht härtegeräts so nah wie möglich an die Oberfläche.
- Laborgebrauch:  
Sandstrahlen Sie mit 25-50 µm-Aluminoxid (0,15 MPa/1,5 bar), reinigen und trocknen Sie die Restauration.  
HINWEIS:  
1) Wenn die Oberfläche noch Ölrückstände aufweist, kann sie mit Ethanol (Alkohol) gereinigt werden. Die Verwendung von Ethanol (Alkohol) auf Acrylaten kann Mikrorisse verursachen.  
Zur Reinigung des Acrylates kann ein mildes Reinigungsmittel verwendet werden.  
2) Wenn OPTIGLAZE color auf Hybrid-Keramik-Blöcke wie CERASMART aufgetragen werden, behandeln Sie die Oberfläche mit CERAMIC PRIMER II (flow dry) und COMPOSITE PRIMER II (light cure) bevor Sie OPTIGLAZE color auftragen.
- Schütteln Sie die Flasche OPTIGLAZE color gut. Bringen Sie ein paar Tropfen in einen Amnischbehälter. Tragen Sie eine dünne Schicht OPTIGLAZE color Ihrer Wahl mit einem Instrument oder einem Pinsel auf die Dentinoberfläche auf (z.B. konvexes und konkaves Dentinamole oder Schneidezahnbereich.) Mischen Sie bei Bedarf mehrere Farben, um den gewünschten Farbton zu erhalten. Trocknen Sie die Schicht nicht mit Luft.
- Härten Sie die Schicht mit einem geeigneten Licht härtegerät. (Siehe Tabelle 1.)
- Bauen Sie den Zahn weiter mit Schmelzfarbe auf der Sauerstoff-Inhibitionsschicht auf. Befolgen Sie die Anweisungen des Komposit-Systems.
- Beenden und polieren Sie auf übliche Weise oder bringen Sie OPTIGLAZE color CLEAR oder CLEAR HV auf die gesamte Oberfläche auf.

Interne Charakterisierung  
1) Bauen Sie die Dentinschicht mit Komposit auf und härten Sie sie mit Licht. Befolgen Sie die Anweisungen des Komposit-Systems.  
Hinweis:  
Die Sauerstoff-Inhibitionsschicht nicht entfernen, sondern Sie die Oberfläche mit CERAMIC PRIMER II (mit Druckluft trocknen) und COMPOSITE PRIMER II (mit Licht härten) bevor Sie OPTIGLAZE color auftragen.  
2) Schütteln Sie die Flasche OPTIGLAZE color gut. Bringen Sie ein paar Tropfen in einen Amnischbehälter. Tragen Sie eine dünne Schicht OPTIGLAZE color Ihrer Wahl mit einem Instrument oder einem Pinsel auf die Dentinoberfläche auf (z.B. konvexes und konkaves Dentinamole oder Schneidezahnbereich.) Mischen Sie bei Bedarf mehrere Farben, um den gewünschten Farbton zu erhalten. Trocknen Sie die Schicht nicht mit Luft.  
3) Härten Sie die Schicht mit einem geeigneten Licht härtegerät. (Siehe Tabelle 1.)

- Bauen Sie den Zahn weiter mit Schmelzfarbe auf der Sauerstoff-Inhibitionsschicht auf. Befolgen Sie die Anweisungen des Komposit-Systems.
- Beenden und polieren Sie auf übliche Weise oder bringen Sie OPTIGLAZE color CLEAR oder CLEAR HV auf die gesamte Oberfläche auf.

Reparatur oder Wiederherstellung (z.B. bei Glanzverlust)  
1) Rauen Sie die zu behandelnde Oberfläche mit einem feinen Schleifpapier auf.  
2) Reinigen Sie die Oberfläche anschließend mit einem Dampfreiniger oder Ultraschallreiniger und trocknen sie mit Öl freier Luft.  
HINWEIS:  
Wenn die Oberfläche immer noch Ölrückstände aufweist, kann sie mit Ethanol (Alkohol) gereinigt werden. Die Verwendung von Ethanol (Alkohol) auf Acrylaten kann Mikrorisse verursachen. Zur Reinigung des Acrylates kann ein mildes Reinigungsmittel verwendet werden.

- Tragen Sie OPTIGLAZE color CLEAR oder den CLEAR HV Farbton auf die Oberfläche auf. Trocknen Sie die Schicht nicht mit Luft.
- Härten Sie die Schicht mit einem geeigneten Licht härtegerät. (Siehe Tabelle 1.)

Table 1: Licht härtezeit	
GC LABOLIGHT DUO	90 Sek.
GC LABOLIGHT LV-III II	5 Min.
GC STEPLIGHT SL-I	Abstand von der Lichtquelle <3 cm 10 Sek. Abstand von der Lichtquelle >3 cm 20 Sek.
Halogenlicht	40 Sek.
Plasma Licht	8 Sek.
LED Licht (mit einer Lichtquelle im Wellenbereich unter 430 nm)	40 Sek.
Table 2: Durch härte tiefe	
Orange, Gelb, Rotbraun, Rot	0,07 mm
A Plus, B Plus, C Plus, Weiß, Elfenbeinweiß, Rosa-Orange, Rosa, Olive, Lavendel, Grau, Blau	0,15 mm
Clear, Clear HV	0,5 mm

**AUFBEWAHRUNG**  
Empfehlung für die optimalen Eigenschaften, Lagerung bei Raumtemperatur zwischen (4-25°C) (39-77,0°F).

**PACKUNG:**  
Komplettes Set:  
A Plus 2,6 mL, B Plus 2,6 mL, C Plus 2,6 mL, Weiß 2,6 mL, Elfenbein-Weiß 2,6 mL, Gelb 2,6 mL, Orange 2,6 mL, Rosa-Orange 2,6 mL, Rosa 2,6 mL, Rotbraun 2,6 mL, Oliv 2,6 mL, Lavendel 2,6 mL, Grau 2,6 mL, Blau 2,6 mL, Rot 2,6 mL, Clear 5 mL, Clear HV 5 mL, Amnischbehälter, Flachpinsel, Rundpinsel

- Stets Schutzkleidung (PSA) wie Handschuhe, Mundschutz und Schutzbrille tragen.
- Vermeiden Sie insbesondere den Kontakt von nicht ausgehärtetem Material mit der Haut.
- Vermeiden Sie, dass Material auf die Kleidung gelangt.
- OPTIGLAZE color ist hochentzündlich und flüchtig. Verwenden Sie das Produkt NIE in der Nähe von offenem Feuer. Halten Sie die Augen während der Anwendung fern.
- OPTIGLAZE color ist flüchtig und kann die Atemwege reizen. Verwenden Sie das Produkt in einem gut belüfteten Raum. Ersetzen Sie die Verschusskappe sofort nach Verwendung der Oberfläche auf.
- Es wird nicht empfohlen, OPTIGLAZE color in Bereichen mit hoher Druckbelastung anzuwenden.
- Kontak mit Produkt mit den Augen in Berührung, spülen Sie sofort mit Wasser und suchen einen Arzt auf.
- Bei Berührung mit der Haut entfernen Sie das Produkt sofort mit einem Schwamm oder einem Wattebausch. Spülen Sie den Bereich mit Wasser.
- Die Sauerstoff-Inhibitionsschicht der zu beschichtenden Kompositoberfläche sollte vor dem Auftragen von OPTIGLAZE color entfernt werden, da sie die richtige Aushärtung von OPTIGLAZE color behindern könnte.
- Bringen Sie ein paar Tropfen OPTIGLAZE color unmittelbar vor der Anwendung in ein Amnischbehälter, da das Material ein flüchtiges Lösungsmittel enthält.
- Unter Verschluss lagern.
- Entsorgen Sie alle Abfälle gemäß den örtlichen Vorgaben.
- In seltenen Fällen kann es sein, dass manche Personen sensibel auf das Produkt reagieren. Falls solche Reaktionen beobachtet werden, stellen Sie den Gebrauch des Produkts ein und wenden sich an einen Arzt.

**REINIGUNG UND DESINFIZIERUNG**  
VERPACKUNG ZUM MEFÄHRICHEN GEBRAUCH: um Kreuzkontaminationen zwischen Patienten zu vermeiden, ist eine Desinfektion mit einem geeigneten Desinfektionsmittel erforderlich. Produkt direkt nach dem Gebrauch auf Abnutzung oder Beschädigung untersuchen. Bei Beschädigung, Material entsorgen.

NIE MALS TAUCHDESINFIZIEREN. Das Material gründlich reinigen und vor Feuchtigkeit schützen, um Kreuzkontaminationen zu vermeiden.  
Desinfizieren Sie mit einem für Ihr Land zugelassenen und registrierten (mid-level registered) Desinfektionsmittel.

Einige Produkte, auf die in der vorliegenden Gebrauchsanleitung Bezug genommen werden, können gemäß dem GHS als gefährlich eingestuft sein. Machen Sie sich immer mit den Sicherheitsdatenblättern vertraut, die unter folgendem Link erhältlich sind:  
<http://www.gceurope.com>

In Amerika gilt folgender Link:  
<http://www.gcamerica.com>  
Wenn Sie sich Unterstützung wünschen, kontaktieren Sie außerdem bei Ihrem Zulieferer anfordern.

Undesirte Wirkungsberichte:  
Wenn Sie sich einer unerwünschten Wirkung, Reaktion oder ähnlichen Vorkommnisse bewusst werden, die durch die Verwendung dieses Produktes erlebt werden, einschließlich derer, die nicht in dieser Gebrauchsanweisung aufgeführt sind, melden Sie diese bitte direkt über das entsprechende Meldesystem, indem Sie die richtige Autorität Ihres Landes zugänglich über den folgenden Link auswählen:  
[https://ec.europa.eu/growth/sectors/medical-devices/contacts\\_en](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en) sowie zu unserer internen Meldestelle: [vigilance@gc.dental](mailto:vigilance@gc.dental)  
Auf diese Weise tragen Sie dazu bei, die Sicherheit dieses Produkts zu verbessern.

Letzte Überarbeitung: 07/2019

## OPTIGLAZE™ color

MATERIAU DE CARACTERISATION PHOTOPOLYMERISABLE

Die Anwendung darf bei empfohlenen Indikationen nur durch einen Zahnarzt/Zahntechniker erfolgen.

### INDICATIONS

- La caractérisation des restaurations directes & indirectes, prothèse à base d'acrylate et de dents artificielles acrylique.
- Pour obtenir une surface lisse et une plus grande résistance à l'abrasion des restaurations en résine composite, prothèses à base d'acrylique et dents artificielles acryliques.

NOTE:  
OPTIGLAZE color n'est pas destiné à la caractérisation des dents naturelles.

### CONTRE INDICATIONS

Eviter d'utiliser ce produit chez des patients présentant une allergie connue aux monomères acrylates / méthacrylates ou polymères acrylates / méthacrylates.

### MODE D'EMPLOI

Caractérisation de surface  
1. Après contourage de la surface de la résine, finissez avec une fraise en carbure ou une pointe de silicone ruvidité. La couche d'inhibition d'oxygène doit être retirée car elle empêche la polymérisation de l'OPTIGLAZE color.

- Utilisation au Laboratoire:  
Sabler à l'alumina 25-50 µm (0,15 MPa/1,5 bar). Nettoyez puis e assécher.  
NOTE:  
1) Si la surface contient des traces de résidu d'huile, la surface peut être nettoyée avec de l'éthanol (alcool). L'utilisation d'éthanol sur la résine acrylique peut entraîner des microfissures. Préférez une solution détergente doux pour nettoyer la résine acrylique.
- Lorsque vous appliquez OPTIGLAZE color sur un bloc céramique hybride comme sur CERASMART, traitez la surface avec CERAMIC PRIMER II.
- Secouez soigneusement le flacon d'OPTIGLAZE color. Mettez quelques gouttes dans le plateau distributeur. Diluez en ajoutant du CLEAR à la teinte désirée. Appliquez une fine couche sur la surface résineuse avec le pinceau fourni. Ne pas souffler d'air.
- Photopolymériser avec une unité de polymérisation adaptée (cf tableau 1). Placez la lumière le plus près possible de la surface.
- Utilisation au Laboratoire : Mettez une plateforme de 2 cm dans l'unité de mérisation et placez la prothèse, sa surface enduite face à la lumière. Retournez la prothèse et répétez la polymérisation pour polymériser entièrement les contours déprimés ou zone d'ombre.

Caractérisation interne  
1) Montage de la couche de dentine avec un composite puis polymériser. Suivez les instructions relatives à votre système composite.  
Note:  
Ne pas retirer la couche d'inhibition par l'oxygène. Appliquez OPTIGLAZE color sur cette couche. Si cette couche est retirée, traitez la surface avec CERAMIC PRIMER II (sécher) et COMPOSITE PRIMER (polymériser) avant d'appliquer l'OPTIGLAZE color.

- Secouez bien le flacon d'OPTIGLAZE color. Distribuez quelques gouttes sur le plateau jetable. Appliquez une fine couche OPTIGLAZE color sur la surface de la dentine avec un instrument ou un pinceau (ex : pinceau dentinaire concave ou convexe ou zone incisale.) Si besoin si tel nécessaire, mélangez les couleurs pour obtenir la teinte désirée. Ne pas sécher à l'air.
- Photopolymériser dans une unité lumineuse adaptée.
- OPTIGLAZE color CLEAR ou CLEAR HV peut être appliqué sur la surface entière après finition et polissage.

Réparation de restauration (ex : perte de brillance)  
1) Raguez la surface de la restauration avec une fraise en carbure et un cône papier  
2) Nettoyez la surface avec un nettoyant vapeur ou ultrason et séchez à l'air propre sans huile.  
NOTE :  
si la surface contient des trace de résidu d'huile, la surface peut être nettoyée avec de l'éthanol (alcool). L'utilisation d'éthanol sur la résine acrylique peut entraîner des microfissures. Préférez un détergent doux pour nettoyer la résine acrylique.  
3) Appliquez une teinte OPTIGLAZE color CLEAR ou CLEAR HV sur la surface. Ne pas sécher.

- Photopolymériser avec une unité lumineuse adaptée.
- OPTIGLAZE color CLEAR ou CLEAR HV peut être appliqué sur la surface entière après finition et polissage.

Tableau 1: Temps de photopolymérisation

GC LABOLIGHT DUO	90 sec.
GC LABOLIGHT LV-III II	5 min.
GC STEPLIGHT SL-I	Distance de la source lumineuse <3 m 10 sec. Distance de la source lumineuse >3 cm 20 sec.
Halogen Light	40 sec.
Plasma Arc	8 sec.
LED Light (avec une source lumineuse ayant une longueur d'onde inférieure à 430 nm)	40 sec.

Tableau 2: Profondeur de polymérisation

Orange Yellow/Red/Brown	0,07 mm
A Plus, B Plus, C Plus, White, Ivory White, Pink Orange, Pink, Olive, Lavender, Grey, Blue	0,15 mm
Clear Clear HV	0,5 mm

**CONSERVATION**  
Pour des performances optimales, conservez à température ambiante entre (4-25°C) (39-77,0°F).

**CONDITIONNEMENT:**  
Coffret complet:  
A Plus 2,6 mL, B Plus 2,6 mL, C Plus 2,6 mL, White 2,6 mL, Ivory White 2,6 mL, Yellow 2,6 mL, Orange 2,6 mL, Pink Orange 2,6 mL, Pink 2,6 mL, Red Brown 2,6 mL, Olive 2,6 mL, Lavender 2,6 mL, Grey 2,6 mL, Blue 2,6 mL, Red 2,6 mL, Clear 5 mL, Clear HV 5 mL, plateau jetable, pinceau plat, cinceau rond.

- Un équipement de protection individuelle (PPE) comme des gants, masques et lunettes de sécurité doit être porté.
- En particulier, évitez le contact peau/matériau non polymérisé.
- Évitez tout contact avec les vêtements.
- OPTIGLAZE color: liquide et vapeur sont hautement inflammables. Ne pas utiliser près d'une flamme nue.
- Évitez de toute source d'ignition, y compris les instruments.
- OPTIGLAZE color est volatile et peut entraîner des irritations respiratoires. A utiliser dans un espace bien ventilé. Replacez immédiatement le capuchon après utilisation.
- Il n'est pas recommandé d'utiliser OPTIGLAZE color dans une zone de haute pression.
- En cas de contact avec les yeux, rincez immédiatement à l'eau et consultez un médecin.
- En cas de contact avec la peau, retirez immédiatement le produit avec une éponge ou une boulette de coton. Rincez à l'eau.
- La couche d'inhibition par l'air de la surface de la résine à enduire doit être retirée avant l'application de OPTIGLAZE color car elle pourrait empêcher une polymérisation correcte de l'OPTIGLAZE color.
- Distribuez quelques gouttes d'OPTIGLAZE color sur un plateau jetable avant application car le matériau contient des solvants volatils.
- Gardez sous clé.
- Éliminer tous les déchets selon la réglementation locale en vigueur.
- Dans de rares cas, ce produit peut provoquer des réactions allergiques. Si tels est le cas, cessez d'utiliser le produit et consultez un spécialiste.

**NETTOYAGE ET DESINFECTIION**  
Systèmes de nettoyage multi-usage: pour éviter toute contamination croisée entre les patients, ce dispositif nécessite une désinfection de niveau intermédiaire. Immédiatement après utilisation, inspecter le dispositif et l'étiqueter, «eter le dispositif s'il est endommagé. NE PAS IMMÉRGER. Nettoyer soigneusement le dispositif pour prévenir l'assèchement et l'accumulation de contaminants. Désinfecter avec un produit de contrôle de l'infection de niveau intermédiaire selon les directives régionales / nationales.

Certains produits mentionnés dans le présent mode d'emploi peuvent être classés comme dangereux selon le GHS. Familiarisez-vous avec les fiches de données de sécurité disponibles sur:  
<http://www.gceurope.com>

ou pour l'Amérique  
<http://www.gcamerica.com>  
Elles peuvent également être obtenues auprès de votre fournisseur.

Declaration d'effets indésirables :  
Si vous avez connaissance d'effets indésirables, de réactions ou d'événements de ce type résultant de l'utilisation de ce produit, y compris ceux non mentionnés dans cette notice, veuillez les signaler directement via le système de vigilance approprié, en sélectionnant l'autorité compétente de votre pays. Contactez-nous à l'adresse suivante:  
[https://ec.europa.eu/growth/sectors/medical-devices/contacts\\_en](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en) ainsi qu'à notre système de vigilance interne : [vigilance@gc.dental](mailto:vigilance@gc.dental)  
Nous vous remercions d'avance pour votre contribution à améliorer la sécurité de ce produit.

Mise à jour: 07/2019

## OPTIGLAZE™ color

MATERIALE FOTOPOLIMERIZZABILE PER CARATTERIZZAZIONE

Per uso esclusivamente professionale nelle indicazioni raccomandate.

### INDICAZIONI RACCOMANDATE

- Caratterizzazione di restauri diretti e indiretti in composito, basi di protesi in acrilico e denti artificiali in acrilico.
- Per ottenere superfici lisce e con elevata resistenza all'usura nei restauri realizzati in resina composita, basi di protesi mobili in acrilico e denti artificiali in acrilico.

NOTE:  
Il prodotto non è stato sviluppato per la caratterizzazione di denti naturali.

### CONTRINDICAZIONI

Evitare di usare il prodotto in pazienti notoriamente affetti da allergie ai monomeri di acrilato / metacrilato o ai polimeri di acrilato / metacrilato.

### ISTRUZIONI PER L'USO

Caratterizzazione delle superfici  
1. Dopo aver definito i contorni della superficie in resina, rifinire con una fresa al carburo o una punta di silicone ruvida. Lo strato di inibizione all'ossigeno deve essere rimosso in quanto impedisce la polimerizzazione di OPTIGLAZE color.

- Impiego in laboratorio:  
Sabbiare l'alumina da 25-50µm (0,15MPa/1,5bar), pulire e asciugare.  
NOTE:  
1) La superficie ancora contiene residui di olio, la si può pulire con etanolo (alcol). L'uso di etanolo (alcol) sulla resina acrilica può causare micro-fratture. Per pulire la superficie acrilica si può utilizzare un detergente delicato.
- Quando si applica OPTIGLAZE color su blocchi di ceramica ibrida come CERASMART, trattare la superficie con CERAMIC PRIMER II.
- Agitare bene la bottella di OPTIGLAZE color. Estrarne alcune gocce su un blocchetto. Diluire aggiungendo CLEAR fino a ottenere il colore desiderato. Applicare uno strato diluito su quanto sottile della superficie di resina usando l'apposito pennello. Evitare di asciugare con getto d'aria.
- Fotopolimerizzare con una lampada idonea (consultare la Tabella 1).
- Photopolymériser avec une unité de polymérisation adaptée (cf tableau 1). Placez la lumière le plus près possible de la surface.
- Inserire una piattaforma da 2 cm nel fotopolimerizzatore e porvi sopra la protesi con la superficie rivestita rivolta verso la luce. Gir



**Dieses Dokument wird Ihnen zur Verfügung gestellt von:**

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