



OPTIGLAZE™

NANOFILLED LIGHT CURED PROTECTIVE COATING FOR COMPOSITE AND ACRYLIC INDIRECT RESTORATIONS

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

INDICATIONS FOR USE

- Coating of indirect composite surfaces (fissures and interproximal areas)
- Coating of denture base surfaces
- Coating of provisional materials

CONTRAINDICATIONS

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

PRECAUTIONS

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

COMPOSITION

Multifunctional monomer, methacrylate, silicon dioxide, initiator

DIRECTIONS FOR USE

Preparation
After contouring the resin surface, finish with carbide bur or coarse silicone 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:

- OPTIGLAZE does not adhere to a polished surface. Make sure surfaces are coated after roughing.
- 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.
- The use of ethanol (alcohol) on acrylic resin may cause micro-cracks. A mild detergent can be used to clean the acrylic resin.

Application

- Dispense a few drops into a dispensing dish. Replace bottle cap immediately after dispensing.
- Immediately apply (within 1 minute after dispensing) to the surface with a brush. DO NOT AIR DRY.

Light Cure
Light curing 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 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.

NOTE:

- If surface is tacky, repeat light curing.
- If necessary, rotate the prosthesis a half-turn or turn-over and light cure again to ensure all surfaces are completely cured.
- Additional build-up cannot be performed on surfaces coated with OPTIGLAZE. Remove the coating layer with a bur and then build-up.
- OPTIGLAZE cannot be cured by a conventional LED light curing device with blue LED only.
- 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 in a cool and dark place (4-25°C / 39-77°F).

PACKAGE

OPTIGLAZE 15 mL (1)

CAUTION

- OPTIGLAZE is flammable. Do not store near open flame. Keep away from sources of ignition. Do not use large quantities in one area. Keep away from direct sunlight.
- OPTIGLAZE is volatile. Use in a well ventilated area. Replace cap immediately after dispensing.
- In case of contact with eyes, flush immediately with water and seek medical attention.
- In case of contact with skin, immediately remove with a sponge or cotton pellet. Flush with water.
- Wear protective gloves. In particular, avoid contact of uncured material with skin.
- Avoid getting material on clothing.
- Avoid inhalation or ingestion of material.
- Do not mix with other products.
- Personal protection: Use of gloves (PPE) such as gloves, face masks and safety eyewear should always be worn.
- 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 safety data sheets available at: <https://www.gcc.dental/europe>

CLEANING AND DISINFECTING

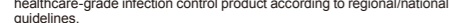
MULTI-USE DELIVERLY SYSTEMS: To avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged. DO NOT IMMERSRE. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level registered healthcare-grade infection control product according to regional/national guidelines.

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

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Last revised: 11/2024



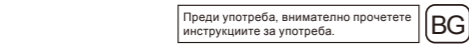
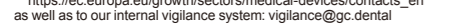
MANUFACTURED BY: GROWTH SYSTEMS

2-GBS Torimatsu-cho, Kasugai, Aichi 486-0844, Japan

DISTRIBUTED BY: GSC CORPORATION

76-1 Hasunuma-cho, Itabashi-ku, Tokyo 174-8585, Japan

EU: GSC EUROPE N.V. Resenschapark Haardroeg-Lusven 1240, Interlevenslaan 33, B-3001 Leuven, Belgium. Tel: +32 16 74 10 100



OPTIGLAZE™

NANOHAŢILNENO FOTOPOLIMERIZIRAJUŐA ZÁŠTITNO POKRITIE ZA KOMPOZITNI I PLÁSTMASOVI INDIKRETI VĚŠTĀŤAVNĀRI

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

INDICATIONS FOR USE

- Pokryvanie na indirektní kompozitní povrchnosti (fissury a mezizubní aproksimální zóny)
- Pokryvanie na osnovata proteza povrchnost
- Pokryvanie na vremenni materialy

CONTRAINDIKACII

Ne ispolzovajte pri pacijentih s ustanoveno alergii kŷm akrilatim ili metakrilaten monomer.

PREDAZNI MERKI

- Ne se preporyvaŷa upotreba na OPTIGLAZE vŷrhu zoni, podložene na golja stres (okluzalni povrchnosti).
- Upotreba na OPTIGLAZE ne zameŷta mehanično poliranje na estetičnitke indirektni kompozitni vŷstanovannia kato GRADIA.

СЪСТАВ

Многoфункционален мономер, метакрилат, силициев диоксид, инициатор

НАСОКИ ЗА УПОТРЕБА

Подготовка
След контуриране на композитната повърхност, завършете с карбиден борер или груба силиконова гума. Почистете повърхността с пароструйка или ултразвук и тогава подсушете. Ако повърхността все още съдържа остатък от масло, тя може да бъде допълнително почиствана с етанол (алкохол).

ЗАБЕЛЕЖКА:

- OPTIGLAZE не се свързва с полирани повърхности. Уверете се, че подложката на покриване повърхности са трапави.
- Използването на инхибитор на полимеризацията на алкохолно или водно покъриване, трябва да бъде отстранен преди нанасянето на OPTIGLAZE, тъй като това може да потисне правилното полимеризиране на OPTIGLAZE.
- Upotreba na etanol (alkohol) vrhu plastmasata polirane na estetičnitke indirektni kompozitni vŷstanovannia kato GRADIA.

Нанасяне

- Дозирайте няколко капки в смесителния съд. Затворете капачката на дозатора веднага след като нанесете.
- ВЕДНАГА нанесете (до 1 минута след дозиране) върху повърхността с чета. НЕ ПОДСУШАВАЙТЕ В СВЪЗДУХ.

Използване на светлинно излъчване
Фотополимеризиране
Фотополимеризирайте с подходящ уред.

LABOLIGHT DUO	90 sec
LABOLIGHT LV-III, II	3 min.
STEPLIGHT SL-I	Vzdálenost od světelného zdroje <3 cm 10 sec Vzdálenost od světelného zdroje >3 cm 20 sec.
Halogenová lampa	40 sek.
LED světlo (s izvorom svetla s vlnovou délkou nižší než 430 nm)	40 sek.

NOTE:

- If surface is tacky, repeat light curing.
- If necessary, rotate the prosthesis a half-turn or turn-over and light cure again to ensure all surfaces are completely cured.
- Additional build-up cannot be performed on surfaces coated with OPTIGLAZE. Remove the coating layer with a bur and then build-up.
- OPTIGLAZE cannot be cured by a conventional LED light curing device with blue LED only.
- 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 in a cool and dark place (4-25°C / 39-77°F).

PACKAGE

OPTIGLAZE 15 mL (1)

CAUTION

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- OPTIGLAZE is volatile. Use in a well ventilated area. Replace cap immediately after dispensing.
- In case of contact with eyes, flush immediately with water and seek medical attention.
- In case of contact with skin, immediately remove with a sponge or cotton pellet. Flush with water.
- Wear protective gloves. In particular, avoid contact of uncured material with skin.
- Avoid getting material on clothing.
- Avoid inhalation or ingestion of material.
- Do not mix with other products.
- Personal protection: Use of gloves (PPE) such as gloves, face masks and safety eyewear should always be worn.
- 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.

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CLEANING AND DISINFECTING

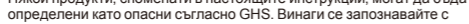
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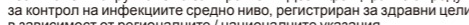
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OPTIGLAZE™

OCHRANNÝ SVĚTLĚN TĚHOUCÍ LÁK S NANOČÁSTICEMI PRO NEPRĚMÉ KOMPOZITNĚ A AKRYLÁTOVÉ VÝPLNĚ VĚŠTĀŤAVNĀRI

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

INDIKACII ZA UPOTREBA

- Ošefeni povrchu nepřímých kompozitních výplní (fisury a mezizubní prostory)
- Ošefeni povrřina baze náhrady
- Ošefeni povrchu provizorních materiálů

CONTRAINDIKACE

Nepoužívejte uporabu ovog proizvoda kod pacijenata s prokazanou alergii na akrilat ili metakrilátový monomer.

UPOTREBA

- Nepodpřipravte monomer používat OPTIGLAZE na vysoce zatěžových místech (okluzální povrchy).
- Použití OPTIGLAZE nenahrazuje mehanično poliranje estetičnik indirektní kompozitních výplní, např. GRADIA.

СЪСТАВ

Многoфункционален мономер, метакрилат, силициев диоксид, инициатор

НАВОД К ПОУЖИТИ

Подготовка
След контуриране на композитната повърхност, завършете с карбиден борер или груба силиконова гума. Почистете повърхността с пароструйка или ултразвук и тогава подсушете. Ако повърхността все още съдържа остатък от масло, тя може да бъде допълнително почиствана с етанол (алкохол).

ЗАБЕЛЕЖКА:

- OPTIGLAZE не свързва с полирани повърхности. Уверете се, че подложката на покриване повърхности са трапави.
- Използването на инхибитор на полимеризацията на алкохолно или водно покъриване, трябва да бъде отстранен преди нанасянето на OPTIGLAZE, тъй като това може да потисне правилното полимеризиране на OPTIGLAZE.
- Upotreba na etanol (alkohol) vrhu plastmasata polirane na estetičnitke indirektni kompozitni vŷstanovannia kato GRADIA.

Нанасяне

- Дозирайте няколко капки в смесителния съд. Затворете капачката на дозатора веднага след като нанесете (до 1 минута по надăvkovani) на поврх. НЕ СУШАЙТЕ ВЪЗДУХ.
- ОДМАХ нанејте (тјеком 1 минута након дозирани) кистом на површину. НЕ KORISTITI PUNALJKU ZA ZRAK.

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Фотополимеризиране
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Halogenová lampa	40 sek.
LED světlo (s izvorom svetla s vlnovou délkou nižší než 430 nm)	40 sek.

NOTE:

- If surface is tacky, repeat light curing.
- If necessary, rotate the prosthesis a half-turn or turn-over and light cure again to ensure all surfaces are completely cured.
- Additional build-up cannot be performed on surfaces coated with OPTIGLAZE. Remove the coating layer with a bur and then build-up.
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STORAGE

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PACKAGE

OPTIGLAZE 15 mL (1)

CAUTION

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- OPTIGLAZE is volatile. Use in a well ventilated area. Replace cap immediately after dispensing.
- In case of contact with eyes, flush immediately with water and seek medical attention.
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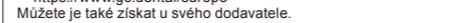
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OPTIGLAZE™

SVJETLOFOTOPOLIMERIZIRAJUŐI ZÁŠTITNI PREAMAZ S NANOPIŦNOLIM ZA KOMPOZITNE I AKRYLÁTNE INDIKRETNĚ RADOVĚ

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

INDIKACII ZA UPORABU

- Premaz indirektní kompozitnih povrřina (fisure i aproksimálna područja)
- Premaz povrřina baze proteze
- Premaz privremeni materijala

CONTRAINDIKACIJE

Nepreporučuje se koristiti OPTIGLAZE na područjima pod visokim opterećenjem (okluzalni povrřina).

Uporaba premaza OPTIGLAZE ne zamjenjuje mehaničko poliranje estetičnik indirektní kompozitnih ispuna kao kod npr. materijala GRADIA.

СЪСТАВ

Вишменски мономер, метакрилат, силици диоксид, инициатор

УПУТЕ ЗА УПОРАБУ

Подготовка
След контуриране на композитната повърхност, завършете с карбиден борер или груба силиконова гума. Почистете повърхността с пароструйка или ултразвук и тогава подсушете. Ако повърхността все още съдържа остатък от масло, тя може да бъде допълнително почиствана с етанол (алкохол).

ЗАБЕЛЕЖКА:

- OPTIGLAZE не припяна за полиране површине. Површине за премаз морају бити прапаве.
- Зракот инхибитор свјетлне акрилатне површине не треба вајта одстранити прије нанасјања светлости на OPTIGLAZE, јер се тиме може спрјечити његово прапавно стврђивање.
- Uporaba etanola (alkohola) na akrilatno moze uzrokovati mikropukotine. Za čišćenje akrilata moze se koristiti blagi deterđent.

Наносење
1. Дозирајте неколико капи у посуду за дозирање. Бојцу одмах поклопити адекватно дозирањем.

2. ОДМАХ нанејте (тјеком 1 минута након дозирани) кистом на површину. НЕ KORISTITI PUNALJKU ZA ZRAK.

Използвање на свјетлано излучвање
Свјетлано полимеризирање
Полимеризирајте одговарајућим уређајем за свјетлано полимеризацију.

LABOLIGHT DUO	90 sec
LABOLIGHT LV-III, II	3 min.
STEPLIGHT SL-I	Udaljenost od izvora svjetla <3 cm 10 sec Udaljenost od izvora svjetla >3 cm 20 sec.
Halogeno svjetlo	40 sek.
LED svjetlo (s izvorom svetla s valnom dužinom niže od 430 nm)	40 sek.

NOTE:

- If surface is tacky, repeat light curing.
- If necessary, rotate the prosthesis a half-turn or turn-over and light cure again to ensure all surfaces are completely cured.
- Additional build-up cannot be performed on surfaces coated with OPTIGLAZE. Remove the coating layer with a bur and then build-up.
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STORAGE

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PACKAGE

OPTIGLAZE 15 mL (1)

CAUTION

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

Enne toote kasutamist lugege hoolikalt kasutamisinghendi.

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OPTIGLAZE™ VALGUSJÄSTAVITLUS NANO-OSAKESTE BAASIL KAITSELAKK INDIKRETSKIVINE KOMPOSIT- JA AKRÜÜLRESTAURATSIOONIDELE

Kasutamiseks ainult handbari spetsialistidele soovitatud kasutusjuhendustele korras.

KASUTUSJÄRGIKUSTUSED
1. Indirektselt komposiidipindade katmine (füssuurid ja interproksimaalsed alad)
2. Põletuste alluspindade katmine
3. Ajustite materjalide katmine

VASTUNDÜSTUSED
Välid toote kasutamisel patsientidel, kellel on kindlaks tehtud allergia akrülaadile või metakrülaatpolümeeride suhtes.

HOIATUSED
1. OPTIGLAZE lakki ei ole soovitat kasutada suurt koormust kandvatel pindadel (oklusioonipinnad).

2. OPTIGLAZE laki kasutamine ei asenda esteetiliselt indirektselt teostatud nagu GRADIA mehaanilist poleerimist.

KOOSTIS
Multifunktsionaalne monomeer, metakrülaat, silikoon dioksiid, iniitsiator

KASUTAMISINGHEND
Ettevalmistus

1. Kui pind on kontamineeritud viimistlege pind karbidpuuri või karede silikonkummiaga. Puhastage pind aurupihusti või ultraheliseadmega ja seejärel kuivatage. Kui pinnal on veel õlisaid jääke, kasutage veel puhastada alkoholia.

TAHKELEPANU:

1. OPTIGLAZE ei kleepu peeleritud pindadele. Veenduge, et kaetavaj pinnad oleks karedad.
2. Enne OPTIGLAZE laki aplikseerimist ei tule valgust pinnalt eemaldada inhibitsiooni kiht, mis võib mõjutada laki korrektselt polümerisatsiooni.

3. Alkoholi kasutamine akrüülvärgi või tekladla mikromõrasis.

Kasutage puhastamisel nõrka alkohooliühust.

Aplikatsioon:

1. Tilgige paar tilka lakki segamisalusale. Sulgege pudel koheselt korgiga.

2. VIIVITAMATULT (1 minuti jooksul) katke pinnad laigika kasutades mikroahelast. ÄRGE JÜSTELDAGE OHTUAG.

Valgusjäästavaime
Valgusjäästavaige sobiva polümerisatsiooniseadmega.

LABOLIGHT DUO	90 sek		
LABOLIGHT LV-III, II	3 min.		
LABOLIGHT DUO	90 sek	Distance no gaismas avota <3 cm	3 min.
LABOLIGHT LV-III, II	3 min.	Distance no gaismas avota >3 cm	20 sek.
STEPLIGHT SL-I	10 sek	Atstumas nuo šviesos šaltinio <3 cm	10 sek.
STEPLIGHT SL-I	20 sek.	Atstumas nuo šviesos šaltinio >3 cm	20 sek.
Halogeenlamp	40 sek.		40 sek.
LED lamp (su izvorom svetla s izvornou džižine nižšou ako 430 nm)	40 sek.		40 sek.

POZNĀMKA:

- Ak je povrch lepivoj, vytvrdzovane zopakujte.
- V prípade potreby odočte náhradu o 180° alebo úplne pretočte a opäť vytvrdzte. Aby ste mali istotu, že všetky povrchy sú úplne vytvrdzené.
- Na povrchoch ošetrovaných OPTIGLAZE nie je možné vykonávať dodatočné dodávky. Odstráňte vrstvu laku bruskom a potom vykonajte dostavbu.
- OPTIGLAZE nie je možné vytvrdzovať beznú LED polymerizačnou lampou len s modrou LED.
- Pri použití polymerizačných lām od iných výrobcov použite režim konečného vytvrdzovania. Postupujte podľa návodu na použitie príslušného výrobcu.

SKLADOVANIE
Pre zachovanie optimálnych fyzikálnych vlastností, skladujte na chladnom a tmavom mieste (4-25°C / 39-77°F).

BALENIE
OPTIGLAZE 15 ml (1)

UPOZORNENIE

- OPTIGLAZE je horľavý. Nepoužívajte v blízkosti otvoreného ohňa. Chráňte pred zdrojmi priameho zápalenia. Neskladujte veľké množstvá v jednom mieste. Chráňte pred priamym slnečným svetlom.
- OPTIGLAZE je prchavý. Používajte na dobre vetranom mieste. Po nadávkovaní nikdy uzavrte vrchnákom.
- V prípade zadržania očí ihneď vypláchnite vodou a vyhľadajte lekársku pomoc.
- V prípade kontaktu s pokožkou ihneď odstráňte hubkou alebo vatovou paličkou. Aplikujte vodou.
- Používajte ochranné rukavice. Vystrýhajte sa najmä kontaktu nevytvrdzenej materiálu s pokožkou.
- Zabráňte znečisteniu uzavrte materiálom!
- Vyhľadajte vhodnú alebo prehrnutú materiálu.
- Nemiešajte s inými výrobkami.
- Vždy používajte ochranné pomôcky ako rukavice, respirátor a ochranný kryt očí.
- V jedinečných prípadoch môže výrobok vyvolať u niektorých osôb precitlivenosť. V takom prípade prerušte používanie výrobku a obráťte sa na lekára.

Niektoré výrobky uvádzané v návode na použitie, môžu byť klasifikované ako nebezpečné podľa GHS. Vždy sa obozrňte s bezpečnostnými kartami, ktoré sú k dispozícii na adrese:
https://www.gcc.dental/europe

Môžete ich tiež získať od svojho dodávateľa.

ČISTENIE A DEZINFEKČIA

DĀVKOVACIE SYTEMY PRE VIACNĀSĀBNÉ POUŽITIE: aby sa zabránilo krížovej kontaminácii medzi pacientami vyžadujú tieto dávkovacie systémy striktnú úroveň dezinfekcie. Ihneď po použití dezinfekcie, či nie je dávkovací systém s štítkom poskodýny. V prípade poškodenia, ho ihneď zlikvidujte.

NEFONĀRĀKATE DO TEKUCĀJ VODY. Dávkovací systém dôkladne očistite, aby sa zabránilo vycpaniu a hromadeniu nečistôt. Dezinfikujte s registrovanými zdravotnými prostriedkami na strednej úrovni dezinfekcie v závislosti na regionálnych / národných smerniciach.

Súhrn bezpečnosti a klinického výkonu (SSCP) nájdete v databáze EUDAMED (https://ec.europa.eu/tools/eudamed) alebo nás kontaktujte na adrese Regulatory.gcc@gcc.dental

Hlásenie nežiadúcich účinkov:
Čo sa zavedte kákršných kŀk neželzých účinkov, reakcij ali podobných dogodkov, do katerých je prŀilo pri uporabi tega izdelka, vkljuĀno s tistimi, ki niso navedeni v tem navodilui za uporabu, jŀ prijavite neposredno prek ustreznega sistema za stŀni nadzor, tako da izberete ustrezen organ v vaši drŀavi dostopni preko naslednjie povezave:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_sl
kŀl tudi v našem sisteme notranjega nadzora: vigilance@gcc.dental
Na ta naĀin boite prispeleli k izboljšanju varnosti tega izdelka.

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en
ako aj na našom vnutorom systeme bdelosti: vigilance@gcc.dental
Týmto spŀsobom prŀispiejete k zvýšeniu bezpeĀnosti tohto výrobku.

Poslednŀ aktualizacia: 11/2024

Prieď preĀadami nauďi aĀiďiďai persalkyke instrukcijas.

Prieď preĀadami nauďi aĀiďiďai persalkyke instrukcijas.

SVĀESA KIETINAMA APSAUGINE MEDIŀAZA NETIESIOGINĒMS KOMPOZĪTO ĀR AKRILĪNĒMS RESTAURĀCIJOMS

Sirkats tik gŀdytojŀ-odontologu naudojimui, pagal rekomenduojamus instrukcijas.

NAUDOJIMO INDIKACIJOS
1. Padengti netiesioginiŀ kompozitŀ restauracijŀ paviršius (vagelĕms, tarpdantiniai ir gŀdymŀ paviršiai).
2. Plietas bŀbes virsmas pŀrkŀbišana
3. Pagaidu materiŀu pŀrkŀbišana

KONTRAINDIKACIJOS
Venkite šio produkto naudojimo pacientams, kuriems pasireikšė jautrumas akrilatŀ ar metakrilatŀ monomerams.

ATSARGUMŲ PRIEMONĖS
1. OPTIGLAZE nerekomenduojama naudoti didelio krantymŀ spaudimo vietoje (okluzijms paviršius).
2. OPTIGLAZE izmantušana neaktivierte netiesio estetiško kompozitu, piemĕram, GRADIA, restauracijŀ mehānisko pulĕšanu.

SĀSTĀVA
Daudzfunkciōnālais monomĕrs, metakrilāts, silikona dioksīds, iniciators

SUDĒTIS
Multifunkciōnis monomĕrs, metakrilāts, silicio dioksīds, iniciatorius

NAUDOJIMO BŪDĀS

Paruģosams
Derivno paviršiusu preparavimŀ uzbakite karbidiniu graŀzeliu ar silikonine taurele. Nuvalykite paviršius garis ar ultragraisnu skaiduliu, tada nusausinkite. Jei restauracijos paviršius dar uŀsteras ribeblas, valykite etilo alkoholia.

PASTABA:

- OPTIGLAZE mediŀaza nelimpa prie poliuruĀto paviršiu. Todĕi jŀsitinkite, jog derinami paviršiai yra tinkami naudoti.
- Paviršinis derius sluoksnis prie OPTIGLAZE aplikavimŀ turĕty bŀti pasalintas, kadangi tai gali trikdyti mediŀazios kietėjimŀ.
- Etanolio (spirit) izmantušana az akrilia svejŀm uŀzraisti mikroplaisius. Akrilia svejŀ atrŀtirimas yra izmantoti maŀu tirŀanos lŀdekli.

Aplikavimas:
1. Jŀ dozavimo indŀ jŀsitinkite kelis lašus mediŀazos. Po dozavimo nedelsiant uzskite buteliukŀ.

2. NĒDELSDAVIETI (1 minutes laikotarpiu nuo dozavimo) ŀepeteliu apbrŀzŀte paviršius. NE NAUDOKITE ORAPŀTES.

Polimerizacija
Ugunis iŀskit atsiemrotu polimerizācijas ierĀi.

LABOLIGHT DUO	90 sek		
LABOLIGHT LV-III, II	3 min.		
LABOLIGHT DUO	90 sek	Distance no gaismas avota <3 cm	3 min.
LABOLIGHT LV-III, II	3 min.	Distance no gaismas avota >3 cm	20 sek.
STEPLIGHT SL-I	10 sek	Atstumas nuo šviesos šaltinio <3 cm	10 sek.
STEPLIGHT SL-I	20 sek.	Atstumas nuo šviesos šaltinio >3 cm	20 sek.
Halogĕna lamp	40 sek.		40 sek.
LED Light (430 nmĕs daŀa duŀa dŀgŀja daĀa boyna saŀip iŀsk kŀnŀgŀi lie)	40 sek.		40 sek.

PIEZĪME:

- Aktŀrotie polimerizācijŀ, ja virsmŀ ir lipĀja.
- Ja nepieciešams, pagrieztet protezes val apgrieztet tŀs, lai visas virsmas tiktu polimerizĕtas.
- Ja uz virsmas ir uzklāts OPTIGLAZE, nav pievienot paglidus negaismos. Tokŀu atveju, nogrieztie apsuŀrij restaurācijas sluoksni ar urbi.
- OPTIGLAZE nevar polimerizĕt ar standartŀ LED gaismas polimerizācijas lampŀ, kurŀ ir tikai zils LED.
- Ja izmantojiet cita raŀotŀja polimerizācijas ierĀtu, pŀielietojt gala polimerizācijas režimŀ. Papildus informācijai skatĀt attiecĀjŀ raŀotŀja lietošanas norādījumus.

UZGLĀBĀŠĀNA
Optimāli izmantušanai lētiemas uzglābāt tumšā un vēsā vietā (4-25°C / 39-77°F) temperatūrā.

ĪPAKOJUMS
OPTIGLAZE 15 ml (1)

BRĪDĪJUMS

- OPTIGLAZE ir uzliesmojōšs. Nelietot atklātas liesmas tuvumā. Neglabāt uzliesmojōšu priekšmetu tuvumā. Neuzglābāt liekus daudzumus vienvieti. Neturēt liekus saules staros.
- OPTIGLAZE mediŀaza yra laki. Naudokite gerai vĕdinamoje patalpoje. Po naudojimo nedelsiant uzardykite buteliukŀ.
- Šis produktas yra pavojingas ir gali sukelti alergines reakcijas ir kŀreipites / gŀdytojus.
- OPTIGLAZE mediŀaza negali bŀti kietinama įprasta LED polimerizavimo lempa.
- Naudodami kitŀ gamintojŀ polimerizavimo prietaisus, juos naudokite finalinio kietinimo režimŀ. Vadovaukitis gamintojŀ nurodytoms rekomendacijoms.

LAIKYMAS
Optimāli izmantušanai lētiemas uzglābāt istabas, laikykite vēsioje, tamsioje vietosie 4-25°C / 39-77°F) temperatūrōje.

PAKUOTE
OPTIGLAZE 15 ml (1)

DĒMOSIS

- OPTIGLAZE yra degus. Nenaudokite šalia atviroos ugnies. Laikykite atokiau nuo degimo šaltiniŀ. Didelio kiekio mediŀazŀ ne laikykite vienoje patalpoje. Saugokite nuo tiesiogios saulės šviesos.
- OPTIGLAZE mediŀaza yra laki. Naudokite gerai vĕdinamoje patalpoje. Po naudojimo nedelsiant uzardykite buteliukŀ.
- Šis produktas yra pavojingas ir gali sukelti alergines reakcijas ir kŀreipites / gŀdytojus.
Eniti valykite vandeniu ir kreipites / gŀdytojus.
- Jei šios mediŀazos paketo ant odos, nedelsiant pašalinkite kempinĕle ar vatine gabaliukŀ. Nuoplukite vandeniu.
- Izvarieties no materiŀa nuokŀjimas az drĕbĕm.
- Venkite mediŀazos pakavimo ant drabuŀiu.
- Venkite mediŀazos kvĕpimŀ ar prarjimŀ.
- Nemaišykite su kitais produktais.
- Asmeninis apsaugos priemonĕs - pirštinĕs, kaukĕs ir apsauginiai akiniai turĕty bŀti naudojami visada
- Kai kuriems pacientams gali pasireikšti padidĕjĕs jautrumas šiam produktui. Jei nustatomos alergines reakcijos – šio produkto vartojimas turĕty bŀti nutraukiamas ir kreipiamasi į gydytojŀ.

Daŀi šis instrukcijas produktŀ sauskŀnŀ ar GHS tiek klasifikacĀi kŀ bŀstami. Iŀpazĕtes ar Drŀbsnas dabŀ lapu var:

https://www.gcc.dental/europe

Tai var saŀgeti arŀ no juos piegādātŀja.

TRĀŠĀNA UN DEZINFĒKĀCIJA

AKRĀTŀRTI LIETOJĀMĀS ĪRĒRCES: lai izvŀrĀtos no šķĕrsinfekcijas starp pacientiem, ŀai ierĀi ir nepieciešams vidĕjŀ lĕmena dezinfekcija. Uzreiz pĕc lietošanas ierĀi un uzlĀmi apskatĀt no virĕtŀts stāvokli. Ja ierĀi ir bojĀti, izāķrtrot lietot nedrĕkt.

NUMĒRCĒTI. Lai izvŀrĀtos no kontaminācijōs vielu noŀzŀšanas un akumulācijas ierĀi pilnĀbŀ notĀrti. Veikt dezinfekciju ar reĀistrĕtu, atlaulu no ŀnĕmektiem infekcijas kontrolei veselības aprūpĕs arĀ, piemĕrotu vidĕjŀ lĕmera produktu, saskatĀt ar reĀionālŀm /valsts vadlĀmĀm.

Drŀbsnas un kliniskĀs veiktŀpas apkopojumu (SSCP) lŀdz ŀklatŀ šķĕrt EUDAMED dabŀ bāzĕi (https://ec.europa.eu/tools/eudamed) vai sazinoties ar Regulatory.gcc@gcc.dental

Nevalĕjam blakusefektiem zinošanas sistĕma:
Ja jums kŀst zināmi jebkĀdi nevēlāmi blakusefekti, reakcija vai līdzīgi notikumi, kas radĀjusies produkta lietošanas laikā, iesakot tādus, kas nav minĕti šĀi produkta lietošanas instrukcijŀ, lĕgums par lĕm zŀgt tiešŀ vigilancas sistĕmā, izvēloties attiecĀgo atbildĀgo iestādi savā valstī, kas ir atrodams šāĀ saitĕ:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en
https://ec.europa.eu/growth/sectors/medical-devices/contacts_en
Tādā veidā jŀs sniegsiet savu ieguldĀjumu uzlabojot produkta lietošanas drošĀbu.

Pĕdĕjŀ reizi pĀrskatĀts: 11/2024

patikslinta: 11/2024

Pirms lietošanas rūpīgi išasetis lietošanas instrukciju.

Pirms lietošanas rūpīgi išasetis lietošanas instrukciju.

OPTIGLAZE™
GAISMA CIETĒ.JOŠS NANOPILNĒLIU AIZSGĀPĀRKĻĀJUMS NETIESĀMS KOMPOZĪTA UN AKRILA RESTAURĀCIJĀM

DrĀkst lietot tikai zobārstniecĀbas speciālisti, kŀ noteikts lietošanas indikācijas.

INDIKĀCIJAS
1. Netiesio kompozitu restaurāciju virsmu pŀrkŀbišana (fĀsoras un proksimālās virsmas)
2. Pliates bŀbes virsmas pŀrkŀbišana
3. Pagaidu materiŀu pŀrkŀbišana

KONTRAINDIKĀCIJAS
Nelietot pacientiem ar alĕrĀju uz akrilātŀ un metakrilātŀ monomĕru.

BRĪDĪJUMS

1. OPTIGLAZE nav lieteicams izmantot uz augstas slodzes virsmŀm (okluzālŀm ŀzferĕm).

2. OPTIGLAZE izmantušana neaktivierte estetiško kompozitu, piemĕram, GRADIA, restauracijŀ mehānisko pulĕšanu.

SĀSTĀVA
Daudzfunkciōnālais monomĕrs, metakrilāts, silikona dioksīds, iniciators

LIETOŠANAS NORĀDĪJUMI

ParuģarĀija
Rezi virsmas konturĕšanas, pabeidzĀt apŀrādi ar kartbada urbuli val raŀu silikona gumu. Virsmu atŀrtiet ar vaiku strĀku vai ultraskaņas ierĀi un pĕc tam nozĀvējĕt. Ja uz virsmas ir palikusi eĀja, to var notĀrt ar etanolu (spirit).

PIEZĪME:

- OPTIGLAZE cilāmŀms ŀzferĕs baglĕmas. PĀbeduēt, lai pŀrkŀbiĀjams virsmas ir raupĀjas.
- KarĀlĀnĀcĀs gaisma izstarojĀmŀs slānis uz kompozita virsmas pirmis OPTIGLAZE aplikēšanas ir jānoņem, jo tas var ietekmĕt OPTIGLAZE polimerizācijas kvalitāti.
- Etanolio (spirit) izmantušana az akrilia svejŀm uŀzraisti mikroplaisius. Akrilia svejŀ atrŀtirāšana var izmantoti maŀu tirŀanos lŀdekli.

Aplikācija:
1. TraucĀni iepilniet daŀus pilienus. Pudĕlti nekavĕjoties noslĕdzĀt.

2. NEKĀVEĀJOTIES uzklĕt (1 minutes laikā no piliena sagatavošanas brĀzi) ar otju uz virsmas. NE LIETOT GAISA STRĀKLU.

Polimerizacija
Ugunis iŀskit atsiemrotu polimerizācijas ierĀi.

LABOLIGHT DUO	90 sek		
LABOLIGHT LV-III, II	3 dak.		
LABOLIGHT DUO	90 sek	Distance no gaismas avota <3 cm	3 min.
LABOLIGHT LV-III, II	3 min.	Distance no gaismas avota >3 cm	20 sek.
STEPLIGHT SL-I	10 sek	Atstumas nuo šviesos šaltinio <3 cm	10 sek.
STEPLIGHT SL-I	20 sek.	Atstumas nuo šviesos šaltinio >3 cm	20 sek.
Halogĕna Light	40 sek.		40 sek.
LED Light (430 nmĕs daŀa duŀa dŀgŀja boyna saŀip iŀsk kŀnŀgŀi lie)	40 sek.		40 sek.

NOT:

- EĀer ŀzferĕ pŀrĀzli ŀze, iŀsk ŀugulamaĀ devam ediniz.
- EĀer gĕrĕkĀies, protezi ŀrĀnu yada tam ters ėvirin ir tŀm ŀzferĕm.
- EĀer ŀzferĕde polimerizāciju saglĀmāsuĀ kādŀr iŀsk ŀugulājinz
- lĀve ŀygt OPTIGLAZE lie otlŀu ŀzferĕs saglĀmāms. Kapli tabakŀy frez lie uzaklĀgŀm ir vĀjĀy ŀpar.
- OPTIGLAZE gaisma LED iŀsk chāzāriem lie polimerize olmaz sadesce mĀv LED lie.
- EĀer ŀrĕticiem iŀsni dŀgŀu chāzi kulnĀliņuvorsu son moduna kullāniz. ŀrĕtiem firmanĀ kullāniz talimatnāms bakimz.

SAKĻAMA
En iŀ performans iŀki, serin ve karānkil bir yerde sakĀyĀn (4-25°C / 39-77°F).

AMBĀLAJ
OPTIGLAZE 15 ml (1)

UYARI

- OPTIGLAZE yanısı ve ıŀcudur. Direk yanısı maddelerin yanında kullanılmaynız. İki kuyuklarımda uzak tutunuz. Direk gŀneye ıyĀndan uzak tutunuz. İyi havalandırm alanlarda kullanınız. Sıkıttıktan sonra kapıyı hemen kapatınız.
- OPTIGLAZE iŀstisizdir. İy havalandırm alanda kullanınız. Sıkıttıktan sonra kapıyı hemen kapatınız.
- OPTIGLAZE iŀstisizdir. İy havalandırm alanda kullanınız. Sıkıttıktan sonra kapıyı hemen kapatınız.
- Uz ferĕmde durumdada direk su lie ıykanınız ve tbbil mŀdahalede bulununuz.
- Deriyem temiz etmesni durumdada, pamuk pelet lie veya spang lie hemen uzaklaĀınız. Su lie ıykanınız.
- Koruyucu eldiven giyiniz. ŀzellikle iŀmne polimerizasyonu u dobre protiravıyomun prımlıcsını. Kuyakırlite plıcsıne kuyısko odrazu plıte vikorıstānız.
- Materiyali solumakınız ve aĀız lie temasından uzak durunuz.
- Diger ŀrĕticiem lie karıstırlınmamalıdır.
- Daıma edınen, ŀzy maskesi ve gŀvenlik gŀzllĀgŀi gibi kŀşleml koruyucu ekipmanlar (KKE) takılmalıdır.
- ŀrĕn ender olarak bazı kŀşlemlere alerjik reaksiyon olugırsabilir. Bu tarz durumdada iŀmne, ŀrĕn kullānılmamı dozajdan ve uzman baŀvurunuz.

Onceki kullanna kilavuzunda refere edilen bazı ŀrĕnler GHS'e gŀre zararlı sınıflandırılmıdır. Daıma kendinizi aŀıđıdaki linke mevcut olan gŀvenlik bilgisi pusulularına alĀırlabılırsınız.
https://www.gcc.dental/europe
Aynı zamanda tedarikcinize edile edilibir.

TEMİZLEME VE DEZENFEKSIYON
ÇOK-KULLANILIMLI DAĞITICI SİSTEM: Hastalar arasında çapraz kontaminasyonu önlemek için bu cihaz orta-seviye dezenfeksiyon ve berekmetektir. Kullanımdan hemen sonra cihaz gŀzlemeye ve bozulma iŀki etkileyen Eger zarar gŀrmeŀse cihazı çŀpe atın.
SUYA DAIĐIRMĀYINIZ. Kurumasını ve kontaminasyonu akümülayyonu no önlemek için tamamen cihazı temizleyiniz. Orta-seviye kuyıtlı saĀık bakim- duraleri etkiniyon kontrol ŀrĕn lie bŀlgesel/ ulusal rehberlere uygun olarak dezenfekte ediniz.

Gŀvenlik ve Klinik Performans ŀzeli™ (SSCP) EUDAMED veritabandan kontrol edebilirsiniz (https://ec.europa.eu/tools/eudamed) veya Regulatory.gcc@gcc.dental adresinden bizimle iletisime geĀebilirsiniz

İstemeyen Etkiler Raporu:
Kullanan talimatında listelenen yan etkiler daha olmak ŀzere, bu ŀrĕn kullānılmıyfa ilgili herhangi bir yan etki (istemeyen etki), reaksiyon veya benzeri olayları tespitli durumdada aŀıđıdaki linke erebilirsiniz.
Prodzenfıkyuē İI zasaov za srednjeg rıvan dezinfekci, jıky zasterrovanıy v ustovov okhorıny dorovıya vıdnoľno do regionalnıkh/natsıonalnıkh smernıcam.

Đla otrımanıya Pıdsumy z Bezpeky ta Klınıkoı Eŀrektıvnostı (SSCP), pereĀetne baıy dınoı EUDAMED (https://ec.europa.eu/tools/eudamed) abo zverıtsıya s nımy za elektrŀnnoı adreseı Regulatory.gcc@gcc.dental

NeĀevlĀnne efekty – Zıvıstıye
Jıky vı dınezıstet pro budı-ne jıbeĀanı naslıdık, reavcı ab vıdnoľno vıdaldı, chıo vıvıslı dınoı kuyıstıyanı chıoıro produkta, vıdnoľno tı chıo ne zınazĀenı v chıı instrukciı chıo vikorıstānıty, budı lıpska.

Prođınoı pro nıo bezpeky dınoı medıcal-devıces/contacts_en
Prođınoı pro nıo bezpeky dınoı