

Prion to use, carefully read the instructions for use.



## CERAMIC PRIMER II

PRIMER FOR CERAMIC AND COMPOSITE BONDING

CERAMIC PRIMER II is a priming agent designed to treat the adherend surface of ceramic and composite prostheses to promote a strong bond to resin-based materials as resin-based cements in case of luting procedures or direct composites in case of repairs.

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

### INDICATIONS FOR USE

1. Priming of the adhering surfaces of indirect restorations made of ceramics (glass ceramics, zirconia and alumina), hybrid ceramics (e.g. CERASMART) and composite before luting indirect restorations made of ceramics, hybrid ceramics and composites.

### CONTRAINDICATIONS

Avoid use of this product in patients with known allergies to methacrylate monomer, methacrylate polymer or ethanol.

### COMPOSITION

Ethanol, dimethacrylate, phosphoric acid ester monomer, silane coupling agent

### DIRECTIONS FOR USE

1. For luting procedure
To treat the bonding surfaces of prostheses according to the respective manufacturer's instructions and then clean it using a suitable cleaning method. We recommend cleaning in an ultrasonic bath or with alcohol, then rinse and dry with an oil-free air syringe.
2. Bottle type: Dispense one drop of CERAMIC PRIMER II into a dispensing dish.
Unit dose type: Unscrew cap of unit dose counter-clockwise. Make sure to identify the top and bottom of the unit dose capsule before opening it.

3. Apply a thin layer to the bonding surface of the ceramic or composite prosthesis using a micro-pip applicator and dry with an air syringe.
4. Apply suitable resin adhesive to the primed surface of the prosthesis. For these steps, refer to the manufacturer's instructions for use of the corresponding luting cement.

For Intra-oral Repair

1. Roughen the bonding surface of ceramic or composite using a coarse diamond bur or a carbundrum point.

2. Treat the bonding surfaces of the prosthesis according to the respective manufacturer's instructions and then clean using a suitable cleaning method. Rinse and dry with an oil-free air syringe.

3. Bottle type: Dispense one drop of CERAMIC PRIMER II into a dispensing dish.

Unit dose type: Unscrew cap of unit dose capsule before opening.

4. Apply a thin layer to the fractured surface of the ceramic or composite prosthesis using a micro-pip applicator and dry with an oil-free air syringe.
5. Continue the repair by using a light-cured adhesive (e.g. G-Premio BOND) and a light-cured composite (e.g. G-anial Universal Flo), referring to their respective manufacturer's instructions for use.

If the treated adherend surface is contaminated with saliva or blood, rinse with water and dry. Re-treat the surface according to the respective manufacturer's instructions and re-apply CERAMIC PRIMER II according to the instructions above.

### STORAGE

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

### PACKAGING

CERAMIC PRIMER II, 1 x 1 bottle of 3 ml
CERAMIC PRIMER II, 10 x unit dose of 0.1 ml

### CAUTION

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

2. Avoid contact with oral tissues. Immediately remove with a cotton pellet or a sponge. Rinse immediately after luting or repairing.

3. In case of contact with skin, remove immediately with a cotton pellet or a sponge. Rinse with water and dry.

4. In case of contact with eyes, flush immediately with water and seek medical attention.

5. Replace the cap of bottle immediately after use. If weak condensation is present on the bottle of CERAMIC PRIMER II, immediately wipe it off.

8. Unit dose is disposable. Do not recar or reuse to avoid cross contamination between patients.

9. If the cap of the unit dose is too tight to open, do not try to open it with force to avoid accidental contact of the liquid with skin and eyes. Use another unit dose.

10. Do not deal with any other primers.

11. Dispose of all waste according to local regulations.

12. In rare cases the product may cause sensitization in some people. If any such reactions are experienced, discontinue the use of the product and consult 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.gce.dental/europe
These products can also be obtained from your supplier.

CLEANING AND DISINFECTING:
MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect correctly and label for deterioration. Discard device if damaged.
DO NOT IMMERS. 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 EUADAMED (https://ec.europa.eu/tools/euadamed) or contact us at Regulatory.gce@gce.dental

Undesired effects - Reporting:
If you become aware of any kind of undesired effect, reaction or similar events experienced by you of this product, including those not listed in this instruction for use, please report them through the relevant vigilance system, by selecting the primary authority of your country accessible through the following link:
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## CERAMIC PRIMER II

ПРИМЕР ЗА СВЪРЗАВАНЕ НА КЕРАМИКА И КОМПОЗИТИ

CERAMIC PRIMER II е подготвящ агент, създаден за здраво залепване на керамични и композитни възстановявания посредством композитни цименти, композитни и приправка на директни композитни възстановявания.

Da se използва само от дентални лекари, спазвайки инструкциите за употреба.

**ИНДИКАЦИИ ЗА УПОТРЕБА**
1. Подготовка на свързващите повърхности на индикретни възстановявания (направени от керамика, цирконий и алуминия), хибридни керамики (напр. CERASMART) и композити преди залепването им.
2. Интраорални и екстраорални препарати на фрактурирани индикретни възстановявания, направени от керамика, хибридна керамика и композити.

**КОНТРАИНДИКАЦИИ**
Избягвайте употребата на този продукт при пациенти с известни алергии към метакрилатен мономер, метакрилатен полимер или етанол.

**СОСТАВ**
Етанол, диметакрилат, мономер естеру киселини фосфорені, силаново съединение

**DIRECTIONS FOR USE**
1. For luting procedure

To treat the bonding surfaces of prostheses according to the respective manufacturer's instructions and then clean it using a suitable cleaning method. We recommend cleaning in an ultrasonic bath or with alcohol, then rinse and dry with an oil-free air syringe.
2. Bottle type: Dispense one drop of CERAMIC PRIMER II into a dispensing dish.
Unit dose type: Unscrew cap of unit dose counter-clockwise. Make sure to identify the top and bottom of the unit dose capsule before opening it.

3. Apply a thin layer to the bonding surface of the ceramic or composite prosthesis using a micro-pip applicator and dry with an air syringe.

4. Apply suitable resin adhesive to the primed surface of the prosthesis. For these steps, refer to the manufacturer's instructions for use of the corresponding luting cement.

For Intra-oral Repair

1. Roughen the bonding surface of ceramic or composite using a coarse diamond bur or a carbundrum point.

2. Treat the bonding surfaces of the prosthesis according to the respective manufacturer's instructions and then clean using a suitable cleaning method. Rinse and dry with an oil-free air syringe.

3. Bottle type: Dispense one drop of CERAMIC PRIMER II into a dispensing dish.

Unit dose type: Unscrew cap of unit dose capsule before opening.

4. Apply a thin layer to the fractured surface of the ceramic or composite prosthesis using a micro-pip applicator and dry with an oil-free air syringe.
5. Continue the repair by using a light-cured adhesive (e.g. G-Premio BOND) and a light-cured composite (e.g. G-anial Universal Flo), referring to their respective manufacturer's instructions for use.

If the treated adherend surface is contaminated with saliva or blood, rinse with water and dry. Re-treat the surface according to the respective manufacturer's instructions and re-apply CERAMIC PRIMER II according to the instructions above.

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

**PACKAGING**
CERAMIC PRIMER II, 1 x 1 bottle of 3 ml
CERAMIC PRIMER II, 10 x unit dose of 0.1 ml

### CAUTION

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

2. Avoid contact with oral tissues. Immediately remove with a cotton pellet or a sponge. Rinse immediately after luting or repairing.

3. In case of contact with skin, remove immediately with a cotton pellet or a sponge. Rinse with water and dry.

4. In case of contact with eyes, flush immediately with water and seek medical attention.

5. Replace the cap of bottle immediately after use. If weak condensation is present on the bottle of CERAMIC PRIMER II, immediately wipe it off.

8. Unit dose is disposable. Do not recar or reuse to avoid cross contamination between patients.

9. If the cap of the unit dose is too tight to open, do not try to open it with force to avoid accidental contact of the liquid with skin and eyes. Use another unit dose.

10. Do not deal with any other primers.

11. Dispose of all waste according to local regulations.

12. In rare cases the product may cause sensitization in some people. If any such reactions are experienced, discontinue the use of the product and consult a physician.

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CLEANING AND DISINFECTING:
MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect correctly and label for deterioration. Discard device if damaged.
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## CERAMIC PRIMER II

PRIMER K BONDOWANIE KERAAMIKI I KOMPOZITU

CERAMIC PRIMER II jest sredstvo za spajanje za nanosenje na otvorene ploscine keramickih i kompozitnih nadgrad na vrhu postojaceg cvrstice na materijalu podloznom. Jednostavno i bezbolno sredstvo za spajanje fiksnih postupa bez kompozitny pri primym kompozitnych opravach.

Určeno vyhradne k pouziti ve stomatologickej praxi v doporučených indikaciach.

### INDIKACIE K POUZITI

1. Priming vzepnych ploch u nepřímých keramických náhrad (sklokeramika, zirkon a oxid hlinitý), hybridní keramiky (např. CERASMART) a kompozitů před nacetováním.
2. Intra-orální a extra-orální opravy zložených nepřímých náhrad z keramiky, hybridní keramiky a kompozitu.

**KONTRAINDIKACE**
Nepoužívejte produkt u pacientů se známou alergií na metakrylátový monomer, metakrylátový polymer nebo etanol.

**SLOŽENÍ**
Etanol, dimethakrylát, monomer esteru kyseliny fosforečné, silanové vazební činidlo

**DIRECTIONS FOR USE**
1. For luting procedure

To treat the bonding surfaces of prostheses according to the respective manufacturer's instructions and then clean it using a suitable cleaning method. We recommend cleaning in an ultrasonic bath or with alcohol, then rinse and dry with an oil-free air syringe.

2. Bottle type: Dispense one drop of CERAMIC PRIMER II into a dispensing dish.

Unit dose type: Unscrew cap of unit dose counter-clockwise. Make sure to identify the top and bottom of the unit dose capsule before opening it.

3. Apply a thin layer to the bonding surface of the ceramic or composite prosthesis using a micro-pip applicator and dry with an air syringe.

4. Apply suitable resin adhesive to the primed surface of the prosthesis. For these steps, refer to the manufacturer's instructions for use of the corresponding luting cement.

For Intra-oral Repair

1. Roughen the bonding surface of ceramic or composite using a coarse diamond bur or a carbundrum point.

2. Treat the bonding surfaces of the prosthesis according to the respective manufacturer's instructions and then clean using a suitable cleaning method. Rinse and dry with an oil-free air syringe.

3. Bottle type: Dispense one drop of CERAMIC PRIMER II into a dispensing dish.

Unit dose type: Unscrew cap of unit dose capsule before opening.

4. Apply a thin layer to the fractured surface of the ceramic or composite prosthesis using a micro-pip applicator and dry with an oil-free air syringe.

5. Continue the repair by using a light-cured adhesive (e.g. G-Premio BOND) and a light-cured composite (e.g. G-anial Universal Flo), referring to their respective manufacturer's instructions for use.

If the treated adherend surface is contaminated with saliva or blood, rinse with water and dry. Re-treat the surface according to the respective manufacturer's instructions and re-apply CERAMIC PRIMER II according to the instructions above.

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

**PACKAGING**
CERAMIC PRIMER II, 1 x 1 bottle of 3 ml
CERAMIC PRIMER II, 10 x unit dose of 0.1 ml

### CAUTION

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

2. Avoid contact with oral tissues. Immediately remove with a cotton pellet or a sponge. Rinse immediately after luting or repairing.

3. In case of contact with skin, remove immediately with a cotton pellet or a sponge. Rinse with water and dry.

4. In case of contact with eyes, flush immediately with water and seek medical attention.

5. Replace the cap of bottle immediately after use. If weak condensation is present on the bottle of CERAMIC PRIMER II, immediately wipe it off.

8. Unit dose is disposable. Do not recar or reuse to avoid cross contamination between patients.

9. If the cap of the unit dose is too tight to open, do not try to open it with force to avoid accidental contact of the liquid with skin and eyes. Use another unit dose.

10. Do not deal with any other primers.

11. Dispose of all waste according to local regulations.

12. In rare cases the product may cause sensitization in some people. If any such reactions are experienced, discontinue the use of the product and consult a physician.

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CLEANING AND DISINFECTING:
MULTI-USE DELIVERY SYSTEMS: to avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect correctly and label for deterioration. Discard device if damaged.
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## CERAMIC PRIMER II

PRIMER ZA SPAJANJE KERAAMIKE I KOMPOZITA

CERAMIC PRIMER II je sredstvo za spajanje za nanosenje na otvorene ploscine keramickih i kompozitnih nadgrad na vrhu postojaceg cvrstice na materijalu podloznom. Jednostavno i bezbolno sredstvo za spajanje fiksnih postupa bez kompozitny pri primym kompozitnych opravach.

Určeno vyhradne k pouziti ve stomatologickej praxi v doporučených indikaciach.

### INDIKACIE K POUZITI

1. Priming vzepnych ploch u nepřímých keramických náhrad (sklokeramika, zirkon a oxid hlinitý), hybridní keramiky (např. CERASMART) a kompozitů před nacetováním.
2. Intra-orální a extra-orální opravy zložených nepřímých náhrad z keramiky, hybridní keramiky a kompozitu.

**KONTRAINDIKACE**
Nepoužívejte produkt u pacientů se známou alergií na metakrylátový monomer, metakrylátový polymer nebo etanol.

**SLOŽENÍ**
Etanol, dimethakrylát, monomer esteru kyseliny fosforečné, silanové vazební činidlo

**DIRECTIONS FOR USE**
1. For luting procedure

To treat the bonding surfaces of prostheses according to the respective manufacturer's instructions and then clean it using a suitable cleaning method. We recommend cleaning in an ultrasonic bath or with alcohol, then rinse and dry with an oil-free air syringe.

2. Bottle type: Dispense one drop of CERAMIC PRIMER II into a dispensing dish.

Unit dose type: Unscrew cap of unit dose counter-clockwise. Make sure to identify the top and bottom of the unit dose capsule before opening it.

3. Apply a thin layer to the bonding surface of the ceramic or composite prosthesis using a micro-pip applicator and dry with an air syringe.

4. Apply suitable resin adhesive to the primed surface of the prosthesis. For these steps, refer to the manufacturer's instructions for use of the corresponding luting cement.

For Intra-oral Repair

1. Roughen the bonding surface of ceramic or composite using a coarse diamond bur or a carbundrum point.

2. Treat the bonding surfaces of the prosthesis according to the respective manufacturer's instructions and then clean using a suitable cleaning method. Rinse and dry with an oil-free air syringe.

3. Bottle type: Dispense one drop of CERAMIC PRIMER II into a dispensing dish.

Unit dose type: Unscrew cap of unit dose capsule before opening.

4. Apply a thin layer to the fractured surface of the ceramic or composite prosthesis using a micro-pip applicator and dry with an oil-free air syringe.

5. Continue the repair by using a light-cured adhesive (e.g. G-Premio BOND) and a light-cured composite (e.g. G-anial Universal Flo), referring to their respective manufacturer's instructions for use.

If the treated adherend surface is contaminated with saliva or blood, rinse with water and dry. Re-treat the surface according to the respective manufacturer's instructions and re-apply CERAMIC PRIMER II according to the instructions above.

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

**PACKAGING**
CERAMIC PRIMER II, 1 x 1 bottle of 3 ml
CERAMIC PRIMER II, 10 x unit dose of 0.1 ml

### CAUTION

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

2. Avoid contact with oral tissues. Immediately remove with a cotton pellet or a sponge. Rinse immediately after luting or repairing.

3. In case of contact with skin, remove immediately with a cotton pellet or a sponge. Rinse with water and dry.

4. In case of contact with eyes, flush immediately with water and seek medical attention.

5. Replace the cap of bottle immediately after use. If weak condensation is present on the bottle of CERAMIC PRIMER II, immediately wipe it off.

8. Unit dose is disposable. Do not recar or reuse to avoid cross contamination between patients.

9. If the cap of the unit dose is too tight to open, do not try to open it with force to avoid accidental contact of the liquid with skin and eyes. Use another unit dose.

10. Do not deal with any other primers.

11. Dispose of all waste according to local regulations.

12. In rare cases the product may cause sensitization in some people. If any such reactions are experienced, discontinue the use of the product and consult a physician.

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## CERAMIC PRIMER II

PRIMER KERAMIAI ÉS KOMPOZIT RAGASZTÁSÁHOZ

A CERAMIC PRIMER II olyan primer, melyet a kerámia és a kompozit pótlások ragasztási felszínének előkészítésére fejlesztettek ki, annak érdekében, hogy a beszállított vagy direkt kompozit helyalkalmazások készítése esetén elősegítse az erős kötést a rezin bázisú anyagokhoz, például rezin bázisú cementhez.

Felhasználás csak szakképzett fogászati személyzetnek javasolt az indikációs területeken.

**ALKALMAZÁSI TERÜLETEK**

1. Kerámiből (üvegerámia, cirkónium-oxid és alumínium), hibrid kerámiből (pl. CERASMART) és kompozitból készült indirekt restaurációk ragasztási felületének előkészítése a ragasztási eljárás előtt.
2. Sérült kerámia, hibrid kerámia és kompozit indirekt restaurációk intraráris és extraráris javítása.

**ELLENÁLLÓTALOK**
Kerülje el a termék használatát metakrilát monomerekre,

