

Prior to use, carefully read the instructions for use.

EN

TEMPSMART™ DC

DUAL-CURED COMPOSITE FOR TEMPORARY CROWN AND BRIDGE

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

INDICATIONS FOR USE

1. Fabrication of temporary crowns, bridges, inlays, onlays and veneers
2. Fabrication of long-term temporary restorations

CONTRAINDICATIONS

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

DIRECTIONS FOR USE

Fabricating temporary restorations

1. Take impression
2. Take the impression using alginate or silicone impression material. Alternatively, temporary can be made using a laboratory-prepared temporary.
3. Block out preparation undercuts.
4. Tools preparation
5. Clean tooth preparation with water spray and lightly dry.
6. Lightly lubricate with separating medium, such as petroleum jelly or propylene teeth or resin core.
7. Dispensing

NOTE: Prior to use of a new syringe or after a long interval between uses, extrude paste from the syringe onto a mixing pad.

1. Remove cap of syringe by rotating 1/4 turn counter-clockwise
2. Block out preparation notch on rim of the mixing tip with a surgical blade. Push firmly to attach the mixing tip. Then repeat the colored cap of mixing tip 1/4 turn clockwise.
3. Discard first centimeter of extruded material before use.

Used mixing tip can be left on syringe to serve as a storage cap until next use. For each application, please a new mixing tip.

4. Posterior tooth preparation
5. Fabricate a temporary crown and bridge material according to timing shown below. Time indicated starts after mixing paste.

Option 1: Fabricating in the mouth

0°00' - 0°45' Place TEMP SMART DC into impression and reposition in mouth.

0°45' - 2°30' Remove impression from teeth.

If necessary, tack each tooth unit with curing light for 1-2 seconds.

Final cure: Remove temporary restoration from mouth and final cure each tooth unit with light curing (high power LED (1200 mW/cm², Halogen + LED (700 mW/cm²) for 5 seconds. Irradiate occlusal surface of temporary crown only, keep temporary restoration in 23°C/74°F for 5'0".

After final cure: Completely remove oxygen inhibition layer from surface of temporary restoration with alcohol.

Option 2: Fabricating in the mouth

0°00' - 0°45' Place TEMP SMART DC into impression and reposition on model.

0°45' - 2°30' Set model.

Final cure: Remove impression from the model and final cure with an extra 5'0" light curing over 1' minute.

If necessary, tack each tooth unit from model.

If chemical cure only, keep temporary restoration in 23°C/74°F until 5'0".

After final cure: Completely remove oxygen inhibition layer from surface of temporary restoration with alcohol.

Caution! Due to high polymerization temperature created, do not irradiate temporary restoration for more than 2 seconds. Do not final cure on tooth.

NOTE: 1) Above processing times are applicable for products stored and processed at a temperature of 23 °C / 74 °F and at 50% relative humidity. Higher temperatures shorten these times, while lower temperatures extend them. The size of the restoration also influences the setting times: as size of restoration increases, setting times increase.

2) When finding, it is important to light cure from the occlusal side of the bridge, irradiate both ends of the bridge alternately.

5) Finishing: 1) Remove excess material using fine carbide bur.

2) Check occlusion and correct shape by using a resin material such as TEMP SMART DC, G-aminal Flo X, G-enial Universal Injectable or UNIFAST Trad, or grind to obtain proper occlusion.

3) Polish surface of temporary restoration using silicone polisher.

4) Use a dental mirror, and, if necessary, apply a coating agent such as OPTIGLAZE or characteris with OPTIGLAZE Color following manufacturer's instructions.

5) If not breathing, polish dust. Use personal protective devices such as face mask and safety glasses.

NOTE: 1) When using a resin material such as TEMP SMART DC, G-aminal Flo X, G-enial Universal Injectable or UNIFAST Trad for a bonding, completely remove saliva contaminated part using a carbide bur. If necessary, apply a ceramic primer such as CERAMIC PRIMER II or G-Multi PRIMER to surface of temporary restoration.

2) When using TEMP SMART DC for custom-shaped and shape correction, light cure mixing paste with curing light for 10' seconds.

6) Cementing: Cement using temporary cement and follow manufacturer's instructions.

NOTE: 7) Remove excess material as it will prevent polymerization of resin.

8) Repairing / Modifying temporary restorations:

1) Abrade surface of temporary restorations using carbide bur.

2) Use a dental mirror, and, if necessary, apply a coating agent such as OPTIGLAZE or characteris with OPTIGLAZE Color following manufacturer's instructions.

NOTE: Completely remove saliva contaminated part using a carbide bur.

9) Finishing: 1) Remove excess material using fine carbide bur.

2) Check occlusion and correct shape by using a resin material such as TEMP SMART DC, G-aminal Flo X, G-enial Universal Injectable or UNIFAST Trad, or grind to obtain proper occlusion.

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NOTE: Completely remove saliva contaminated part using a carbide bur.

9) Finishing: 1) Remove excess material using fine carbide bur.

2) Check occlusion and correct shape by using a resin material such as TEMP SMART DC, G-aminal Flo X, G-enial Universal Injectable or UNIFAST Trad and cure according to manufacturer's instructions.

NOTE: Completely remove saliva contaminated part using a carbide bur.

10) In case of contact with oral tissue or skin, remove immediately with cold water and apply a cold compress. If necessary, contact a rubber band and/or COCOA BUTTER can be used to isolate operating area from skin or oral tissue.

11) In case of eye contact, flush immediately with water and seek medical attention.

12) Do not use eye drops, flush immediately with water and seek medical attention.

13) Protect eye glass during light curing.

14) Avoid getting material on clothing, use a dental mirror, and remove with water.

15) Mixing tips are for single use only. To prevent cross contamination between patients, do not reuse the mixing tip. The mixing tip cannot be sterilized.

16) Personnel protective equipment (PPE) such as gloves, face mask and safety eyewear should always wear. Wearing glove during use avoid any contact with any patient residue in order to prevent possible sensitivity.

17) Wear protective eye glasses during light curing.

18) Avoid getting material on clothing, use a dental mirror, and remove with water.

19) Avoid getting material on clothing, use a dental mirror, and remove with water.

20) Do not use eye drops, flush immediately with water and seek medical attention.

21) CARTRIDGE DISPENSER II (1)

22) GRADIA CORE DISPENSER GUN (1)

SHADES

A1, A2, A3, A5, B1 and BW

STORAGE

Recommended for optimal performance, store in a cool and dark place (4°25°C / 39-22.7°F) away from high temperatures or direct sunlight.

PACKAGES

Reference

1. Cartridge 48ml. (60g) (1), MIXING TIP II SSS (16)

2. Cartridge 12.5ml. (12.5g) (1), GC Automic Tip Regular (10)

3. Mixing tip package

1. MIXING TIP II SSS (60)

2. GC Automic Tip Regular (20)

4. GRADIA CORE DISPENSER GUN (1)

CAUTION

1. In case of contact with oral tissue or skin, remove immediately with cold water and apply a cold compress. If necessary, contact a rubber band and/or COCOA BUTTER can be used to isolate operating area from skin or oral tissue.

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10. Do not use eye drops, flush immediately with water and seek medical attention.

11) Do not use TEMP SMART DC in combination with eugenol containing materials as eugenol may delay or prevent TEMP SMART DC from curing.

12) Do not mix with toluene with excessive alcohol as this may cause contamination of the paste.

13) Dispose of all wastes according to local regulations.

14) In case of eye contact, flush immediately in some people. If any such reactions are experienced, discontinue use of the product and refer to a physician.

Some products referred in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheet of your supplier.

http://www.gecureurope.com

They can also be obtained from your supplier.

CLEANING AND DISINFECTION: To avoid cross-contamination between different dental systems, use individual disinfection device if damaged.

DO NOT IMMERSIVE: Thoroughly clean device to prevent drying and accumulation of contaminants. Dismantle with a rigid medical instrument for decontamination control according to regional/international guidelines.

Undesired effects - Reactions of the system: There are no known kind of undesired effect, reaction or similar events experienced by this product, including those not listed in this instruction for use, including those through the relevant website, and the consumer authority of your country accessible through the following link:

https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

as well as to our internal vigilance system: vigilance@gecureurope.com

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

Last Revised: 08/2019

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Alternatively, temporary can be made using a laboratory-prepared temporary.

2. Block out preparation undercuts.

3. Tools preparation

4. Cleaning tooth preparation with water spray and lightly dry.

5. Lightly lubricate with separating medium, such as petroleum jelly or propylene teeth or resin core.

6. Dispensing

NOTE: Prior to use of a new syringe or after a long interval between uses, extrude paste from the syringe onto a mixing pad.

1. Remove cap of syringe by rotating 1/4 turn counter-clockwise

Alternatively, push the mixing pad onto rim of the mixing tip with a surgical blade. Push firmly to attach the mixing tip. Then repeat the colored cap of mixing tip 1/4 turn clockwise.

2. Discard first centimeter of extruded material before use.

Used mixing tip can be left on syringe to serve as a storage cap until next use. For each application, please a new mixing tip.

4. Posterior tooth preparation

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0°45' - 2°30' If necessary, tack each tooth unit with curing light for 1-2 seconds.

Final cure: Remove impression from teeth.

If necessary, tack each tooth unit with curing light for 1-2 seconds.

After final cure: Completely remove oxygen inhibition layer from surface of temporary restoration with alcohol.

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0°00' - 0°45' Place TEMP SMART DC into impression and reposition on model.

0°45' - 2°30' Set model.

Final cure: Remove impression from the model and final cure with an extra 5'0" light curing over 1' minute.

If necessary, tack each tooth unit from model.

If chemical cure only, keep temporary restoration in 23°C/74°F until 5'0".

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Pred použitím sa dodávajú prečíle návod na použitie SK

TEMPSMART™ DC

DÁLNE TUHÚNÍ KOMPOZIT PRE DOČASNÉ KORUNKY A MOSTIKY

Uzávereň využívané na použitie v oblasti stomatologickej pre nasledovné indikacie:

INDIKÁCIE NA POUŽITIE:

1. Zhotovenie dočasných korunk, mostíkov, inlejí, onlejí a fazeí
2. Zhotovenie dlhotrvajúcich náhrad

KONTRAINDIKÁCIE:

Tento kompozit je určený iba pre pacientov s zistenou alergiou na metakrilátový monomer alebo metakrilátový polymer.

NÁVOD NA POUŽITIE:

Zhotovenie dočasného náhrad:

- 1) Odstráňte odťahok pomocou digitnej alebo silikonovej odťahovej pásky. Prípadne je možné dočasne používať laboratórnu prípravku tepelnú farbu.

2. Vložte dočasnu náhradu:

- 1) Vložte kultúpku podľašivú mestu preparovaného žuba.

3. Použite vložku:

- 1) Vložku kultúpku podľašivú mestu preparovaného žuba.

4. Použite vložku:

- 1) Vložku kultúpku mestu dočasnej náhrady.

5. Vložte dočasnu náhradu:

- 1) Vložte dočasnu náhradu dočasnej náhrady.

6. Použite vložku:

- 1) Vložku kultúpku mestu dočasnej náhrady.

7. Použite vložku:

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