

**TEMPSMART**

DUAL-CURED COMPOSITE FOR TEMPORARY CROWN AND BRIDGE

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

**RECOMMENDED INDICATIONS**

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

**CONTRAINDICATIONS**

Avoid use of this product in patients with known methacrylate monomer and methacrylate polymer allergies.

**DIRECTIONS FOR USE**

Fabricating temporary restorations

## 1. Taking impression

- Take impression using alginate or silicone impression material. Alternatively, temporary can be made using a laboratory-prepared thermoforming matrix.
- Block out preparation undercuts.
- Tooth preparation
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- Clean tooth preparation with water spray and lightly dry.
- Lightly lubricate with separating medium, such as petroleum jelly on prepared teeth or resin core.
- Dispensing

NOTE: Before dispensing first time from a new syringe or after a long interval between uses, bleed pastes from the syringe.

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

Attach a Mixing Tip by aligning V shaped notch on rim of the mixing tip with V shaped notch between syringe barrels. Push firmly to attach the mixing tip. Then rotate the colored collar of mixing tip 1/4 turn clockwise.

2) Discard first centimeter of extruded material before use.

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

4. Fabricating a temporary restoration

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 TEMPSMART into impression and reposition in mouth.

0'45"-2'00" Setting in mouth.

2'00"-2'30" Remove impression from teeth.

If necessary, tack cure 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 unit (Plasma Arc (2000 mW/cm²), G-Light (1200 mW/cm²), Halogen / LED (700 mW/cm²)) for 5 seconds. Irradiate occlusal surface. If chemical cure only, keep temporary restoration in 23°C/74°F until 5'00".

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

Option 2: Fabricating on the model

0'00"-0'45" Place TEMPSMART into impression and reposition on model.

0'45"-3'00" Setting on model.

Final cure Remove impression from the model and final cure with an extra oral light curing oven for 1 minute.

Remove temporary restoration from model.

If chemical cure only, keep temporary restoration in 23°C/74°F until 5'00".

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 has impact on setting times: as size of restoration increases, setting takes longer.

2) When irradiating temporary crown and bridge, irradiate occlusal surface.

3) When final curing temporary crown and bridge with curing light, irradiate one tooth from both ends first to prevent deformation.

5. Finishing

1) Remove excess material using fine carbide bur.

2) Check occlusion and if necessary, correct shape by using a resin material such as TEMPSMART, G-aenial Flo, G-aenial Universal Flo or UNIFAST Trad, or grind to obtain proper occlusion.

3) Polish surface of temporary restoration using silicone polisher and goat's hair wheel. Alternatively, apply a coating agent such as OPTIGLAZE or characterize with OPTIGLAZE Color following manufacturer's directions.

Caution! Do not breathe in polishing dust. Use personal protective devices such as facemask and safety glasses.

NOTE: 1) When using a resin material such as TEMPSMART, G-aenial Flo, G-aenial Universal Flo or UNIFAST Trad for custom-shaping and shape correction, usually there is no need for a bonding agent.

Completely remove saliva contaminated part using a carbide bur.

If necessary, apply a ceramic primer such as CERAMIC PRIMER II to surface of temporary restoration.

2) When using TEMPSMART for custom-shaping 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: Do not use eugenol cement as it will prevent polymerization of resin.

Repairing / Modifying temporary restorations

1) Abrade surface of temporary restorations using carbide bur.

2) If necessary, apply a ceramic primer such as CERAMIC PRIMER II and dry with air.

3) Place a resin material such as TEMPSMART, G-aenial Flo, G-aenial Universal Flo or UNIFAST Trad and cure according to manufacturer's instructions.

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

SHADES A1, A2, A3, A3.5, B1 and BW

**STORAGE**

Recommended for optimal performance, store in a cool and dark place (4 - 25°C / 39.2 - 77.0°F) away from high temperatures or direct sunlight. (Shelf life: 2 years from date of manufacture, note expiration date)

**PACKAGES**

Refills:

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

2. Cartridge 10mL (12.5g) (1), GC Automix Tip Regular (10)

Mixing tip package:

1. MIXING TIP II SSS (GC) (60)

2. GC Automix Tip Regular (20)

Dispenser package:

1. CARTRIDGE DISPENSER II (GC) (1)

2. GRADIA CORE DISPENSER GUN (1)

**CAUTION**

1. In case of contact with oral tissue or skin, remove immediately with cotton or a sponge soaked in alcohol. Flush with water. To avoid contact, a rubber dam and/or cocoa butter can be used to isolate operating field from skin or oral tissue.

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

3. Take care to avoid ingesting material.

4. Do not mix with components of other products.

5. 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 in an autoclave or chemicalclave.

6. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn. Wearing gloves during use avoids direct contact with air inhibited resin in order to prevent possible sensitivity.

7. Wear protective eye glasses during light curing.

8. When polishing polymerized material, use dust collector and wear a dust mask to avoid inhalation of dust.

9. Avoid getting material on clothing.

10. In case of contact with unintended areas of tooth or prosthetic appliances, remove with instrument, sponge or cotton pellet before light curing.

11. Do not use TEMPSMART in combination with eugenol containing materials as eugenol may delay or prevent TEMPSMART from setting.

12. Do not wipe mixing tip with excessive alcohol as this may cause contamination of the paste.

13. Dispose of all wastes according to local regulations.

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

**CLEANING AND DISINFECTION:**

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 IMMERSE. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level registered health care 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.gcamerica.com>

They can also be obtained from your supplier.

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**TEMPSMART**

RESINA DE POLIMERACIÓN DUAL PARA PUENTES Y CORONAS TEMPORALES

Para uso exclusivo por profesionales dentales, siguiendo estas instrucciones.

**USOS RECOMENDADOS**

- Fabricación de coronas y puentes temporales, inlays, onlays y carillas (veneers)
- Elaboración de provisionales a largo plazo.

**CONTRAINDICACIONES**

Evite el uso de este producto en pacientes que presenten alguna alergia al monómero de metacrilato y/o polímeros de metacrilato.

**INSTRUCCIONES DE USO**

Fabricación de restauraciones temporales

1. Tome una impresión

1) Tome una impresión usando alginate o material para impresiones a base de silicona. Alternativamente, el temporal puede ser fabricado usando un matriz de termo-formado en laboratorio.

2) Bloque cualquier retención existente.

3. Preparación del diente

1) Bloque cualquier retención existente.

2) Limpie la preparación del diente rociando con agua y seque ligeramente.

3) Lubrifique ligeramente con un medio separador, como la vaselina, en la preparación del diente o en el cuerpo de la resina.

4. Dispense

NOTA:

Antes de dispensar por primera vez una nueva jeringa, despues de no haber utilizado la jeringa por mucho tiempo, purge las pastas de la misma.

1) Retire la tapa de la jeringa girando 1/4 de vuelta hacia la izquierda.

Coloque una punta mezcladora alineando la muesca en forma de V en el borde de la punta mezcladora con la muesca en forma de V entre las jeringas. Empuje con firmeza para fijar la punta mezcladora.

A continuación, gire el cuello de color de la punta mezcladora 1/4 de vuelta en sentido horario.

2) Deseche el primer centímetro de material extruido antes de su uso.

3) Dispense el material directamente en la impresión.

NOTA:

La punta mezcladora utilizada puede ser dejada en la jeringa para servir como tapa para almacenar hasta su siguiente uso. Utilice una nueva punta mezcladora para cada aplicación.

4. Fabricando una restauración temporal

Fabricar una corona o Puente temporal de acuerdo a los tiempos mostrados a continuación. El tiempo indicado incluye después de mezclar la pasta.

Opción 1: Fabricación en boca

0'00"-0'45" Dispense TEMPSMART en la impresión y coloque en la boca.

0'45"-2'00" Curado en boca

2'00"-2'30" Remueva la impresión de los dientes. Si es necesario, retoque el curado de cada diente individualmente con una lámpara de fotocurado por 1-2 segundos.

Curado final

Remueva la restauración temporal de la boca y cure finalmente cada diente individualmente utilizando una lámpara de fotocurado girando la boca en forma de V.

Coloque una punta de mistura alineando la muesca en forma de V entre las jeringas. Empuje firmemente para fijar la punta de mistura.

En seguida, gire la gola colorida de la punta de mistura 1/4 de vuelta en sentido horario.

2) Descarte los primeros centímetros del material extruido antes de uso.

3) Dispensar

NOTA:

Antes de dispensar material de una nueva seringa, pela la primera vez ou depois de não utilizar a seringa por um longo período de tempo, drene a pasta de seringa.

1) Remova la tampa de la seringa, rodando 1/4 de vuelta para la esquina.

Coloque una punta de mistura alineando la muesca en forma de V entre las jeringas. Empuje firmemente para fijar la punta de mistura.

2) Describa los primeros centímetros del material extruido antes de uso.

3) Dispensar el material directamente en la impresión.

NOTA:

A punto de mistura puede ser utilizada na seringa como tampa para armazenar até sua próxima utilização. Utilize uma nova ponta de mistura para cada aplicação.

4. Confecionando una restauración temporal

Fabricar una corona oportuna o ponte de acuerdo con os tempos mostrados abajo. Comprece tempo indicado após a mistura da massa.

Opción 1: Confecção em boca

0'00"-0'45" Dispense TEMPSMART na impressão e posicione na boca do paciente.

0'45"-2'00" Polimerização em boca

2'00"-2'30" Remover la impresión dos dientes. Si es necesario, retoque a polimerización de cada diente individualmente con o fotopolimerizador por 1 a 2 segundos.

Cura final

Remova la restauración temporal de la boca e, finalmente, polimerizar cada diente individualmente usando um fotopolimerizador (Arco de plasma (2000 mW/cm²), G-Light (1200 mW/cm²), Halógeno / LED (700 mW/cm²)) por 5 segundos. Polimerize na superficie oclusal. Se você usar apenas cura química, mantenha restauração temporária a 23 graus Celsius durante 5 minutos.

Após cura final

Usando un algodón embebido en álcool, remova completamente la capa inhibitoria de oxígeno de la superficie de la restauración temporal.

Después de curado final

Utilizando una torunda con alcohol, remueve completamente la capa inhibitoria de oxígeno de la superficie de la restauración temporal.

Option 2: Fabricación en Model

0'00"-0'45" Dispense TEMPSMART en la impresión y reponga en el modelo.