



G-CEM ONE™ Paste Pak SELF-ADHESIVE RESIN CEMENT

G-CEM ONE™ ADHESIVE ENHANCING PRIMER

TOOTH PRIMER FOR G-CEM ONE

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

INDICATIONS FOR USE

- Cementation of all types of all ceramic, resin and metal-based inlays, onlays, crowns and bridges.
- Cementation of metal, ceramic, fiber posts, cast post and cores.
- Cementation of all ceramic and composite veneers.
- Final cementation of crowns and bridges on implant abutments.

CONTRAINDICATIONS

- Direct pulp capping.
- Avoid use of the product in patients with known allergies to methacrylate monomer, methacrylate polymer or ethanol.

IDENTIFICATION OF PARTS (Fig. 1)

- Paste Pak Cartridge
- Core
- Sliding block
- Cartridge tip
- Adjusting guide
- Piston
- Sliding block
- Lever
- Piston release

DIRECTIONS FOR USE

Mixing Time (sec.) 10"

Working Time (23°C / 73°F) (min., sec.) 2'30"

Finishing Time (37°C / 99°F, after excess cement removal) (min., sec.) 4'00"

PASTE PAK CARTRIDGE LOADING

1. Make sure that the piston is completely retracted into the dispenser (Fig. 2).

NOTE: To retract the piston, push the piston release and at the same time pull the sliding block (on the underside of the dispenser) with fingers.

2. Load the cartridge into the Paste Pak Dispenser (Fig. 3).

Ensure the ▲ mark on the cartridge lines up with the ▲ mark on the Paste Pak Dispenser as illustrated. Then turn the cartridge fully to the right position.

NOTE: To remove the cartridge, retract the piston fully and turn the cartridge back to the marked positions.

3. After cartridge loading, push the piston release forward until it stops (Fig. 4).

a) Push the piston release forward.

b) Do not push the upper side.

A. CEMENTATION TECHNIQUE for all inlays, onlays, crowns, bridges and veneers

1. TOOTH PREPARATION

a) Prepare the tooth in the manner:

b) Clean the prepared tooth with pumice and water. A clean surface is paramount for an optimal adhesion.

c) Rinse thoroughly with water. Dry thoroughly by gently blowing with oil free air. Prepared surface should be dry.

d) In case of hybrid veneer preparation where extra adhesion is needed, apply G-CEM ONE ADHESIVE ENHANCING PRIMER to adhesive surface.

e) In case of veneer or onlay cementation, enamel etching with 35% phosphoric acid should be done for 10-15 seconds and rinse off with water. Application of G-CEM ONE ADHESIVE ENHANCING PRIMER to adhesive surface.

f) In case of hybrid ceramic cementation (such as CERAMSMART270), G-CEM ONE ADHESIVE ENHANCING PRIMER should be applied to the adhesive surface.

NOTE: 1. Do not use substances like H₂O₂, EDTA and/or disinfectants as these may lower the bond strength.

2. Special care should be taken to remove imaging powders very thoroughly with pumice and water.

2. APPLICATION OF G-CEM ONE ADHESIVE ENHANCING PRIMER (Optional)

a) Dispense a few drops into a clean dispensing dish. Close the bottle cap immediately.

b) IMMEDIATELY apply to the prepared enamel and dentin surfaces using the disposable applicator.

c) Leave undisturbed for 10 seconds after the end of application.

d) Dry thoroughly for 5 minutes with oil free air under MAXIMUM air pressure. Use vacuum suction to prevent splatter of the adhesive.

3. RESTORATION PREPARATION

Make sure that the restoration is pretreated and handled according to the manufacturer's instructions.

a) For Glass Ceramics, hybrid ceramics and composite, apply a silane coupling agent to the bonding surface, such as G-Multi PRIMER and dry with an air syringe.

4. DISPENSING

a) Remove the cartridge cover. (Fig. 5)

b) Depress the lever to dispense the required amounts of paste onto the mixing pad.

NOTE: 1. Before dispensing the first time from a new cartridge or after a long interval in between use, bleed the pastes from the cartridge. (Fig. 6)

2. The adjusting guide can be moved forwards or backwards to change the quantity of material to be dispensed. (Fig. 7)

3. Position of adjustment guide for one crown.

c) While depressing the lever (Fig. 8, level) and cut off the extruded material from the cartridge tip by moving the cartridge and dispenser to an upright position on the mixing pad. (Fig. 8-2)

d) When dispensing, do not allow individual pastes at the cartridge tips are retracted into the cartridge. Clean the cartridge tip and replace the cartridge cover. (Fig. 9)

NOTE: 1. The amount of residual material in the cartridge can be confirmed by the position of the sliding block on the underside of the dispenser.

5. MIXING

After dispensing, mix the two pastes firmly on the mixing pad using a plastic spatula. Mix thoroughly, by tapping strokes, for 10 seconds. Be careful not to incorporate air bubbles.

6. CEMENTATION

a) Coat the internal surface of the restoration with sufficient cement and seat immediately. The working time is 2 minutes 30 seconds from start of mix at 23°C (73°F). Higher temperatures will shorten the working time.

b) 1. Ambersil may shorten the working time. It is recommended to diminish the intensity or turn off your operation light during the cementation procedure.

c) When the cement is in contact with G-CEM ONE ADHESIVE ENHANCING PRIMER, the setting reaction is accelerated.

d) In case of veneer cementation, it is recommended to cement a minimum of one veneer at a time due to relatively short working times.

e) Maintain moderate pressure until final finishing is done.

7. EXCESS CEMENT REMOVAL

a) Remove excess cement using one of the techniques below:

1. Tack cure by using the light guide of a curing light over the excess cement. Wait until the excess cement has a slight consistency and remove the excess cement using a probe or another appropriate instrument. Reaching a good consistency for excess cement removal depends on the light curing unit being used. It is important to find the optimum time of exposure of time, intensity and distance of the curing light in use.

2. Keep moderate pressure and remove excess cement using a brush. Make sure that excess cement is thoroughly removed from areas of difficult access (e.g. interproximal areas).

3. Avoid the oxygen inhibition layer at the margins of the restoration, protect the margins with a glycerin gel after removing the excess cement.

8. FINAL SET

While maintaining moderate pressure, light cure all surfaces / margins. Refer to the following chart for irradiation time.

Irradiation time

High power LED (more than 1200 mW/cm²) 10 seconds

Halogen / LED (700-1200 mW/cm²) 20 seconds

In case of the following materials, let the material set for 4 minutes after the final set of cement.

- Metal and metal coping restorations

- Metal-free dark and opaque restorations

- Translucent metal-free restorations greater than 2 mm in thickness

9. FINAL POLISHING

If needed, finish and polish margins with appropriate instruments.

B. CEMENTATION TECHNIQUE for metal, ceramic, fiber posts, and cast post and cores

1. TOOTH PREPARATION

Prepare the post space according to manufacturer's instructions. The post space should be cleaned, rinsed and dried thoroughly using paper points. The post space should be dry. If the adhesive needs to be applied to the post space, apply G-CEM ONE ADHESIVE ENHANCING PRIMER to adhesive surface prior to application of the post.

2. POST PREPARATION

Make sure that the post is pretreated and handled according to the manufacturer's instructions.

3. DISPENSING & MIXING

Refer to A. and A. 5.

4. CEMENTATION

a) Apply the cement on adhesive surface of the post.

b) Place the post immediately into the post space. Be careful not to incorporate air bubbles enter the root canals.

NOTE: 1. The oral temperature accelerates the setting reaction of the cement.

2. Ambersil may shorten the working time. It is recommended to diminish the intensity or turn off your operation light during the cementation procedure.

3. DO NOT use lateral spirals to place the cement in the post space as this may shorten the setting reaction.

4. When the cement contains G-CEM ONE ADHESIVE ENHANCING PRIMER, the setting reaction is accelerated.

5. EXCESS CEMENT REMOVAL

Continue to maintain moderate pressure making sure the post remains in place. Use a probe or appropriate instrument with appropriate instruments. In case of a cast post and core, tack cure all surface for 1 second each with a visible light curing unit.

6. FINAL SET

a) While maintaining moderate pressure, light cure all surfaces / margins. Refer to the following chart for irradiation time.

Irradiation time

High power LED (lebih dari 1200 mW/cm²) 10 detik

Halogen / LED (700-1200 mW/cm²) 20 detik

b) Let the material set for another 4 minutes.

CLEANING & STERILIZATION OF PASTE PAK DISPENSER

For cleaning and sterilization of PASTE PAK DISPENSER, refer to the respective instructions for use.

STORAGE

Recommended for optimal performance, store at temperature of 4-25°C (39.2-77.0°F) away from heat, moisture and direct sunlight.

SHADE

A2 (Vita® shade), AO3 (opaque), White Opaque, Translucent

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PACKAGES

1. G-CEM ONE Paste Pak Starter kit (A2, Translucent):

- G-CEM ONE Paste Pak Cartridge (7.6 ml.) (1), G-CEM ONE ADHESIVE ENHANCING PRIMER (2.6 ml.) (1), Mixing Pad (No.22) (1)

2. G-CEM ONE Paste Pak Single Refill (A2, AO3, White Opaque, Translucent):

- G-CEM ONE Paste Pak Cartridge (7.6 ml.) (1), Mixing Pad (No.22) (1)

CAUTION

1. In case of contact with oral tissue or skin, remove immediately with a sponge or cotton ball saturated with water. To avoid contact, a rubber dam and/or COCOA BUTTER can be used.

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

3. Do not use G-CEM ONE Paste Pak in combination with eugenol containing materials as eugenol may hinder G-CEM ONE Paste Pak from setting or bonding properly.

4. Use a protective light shield or similar protective eye wear during light curing.

This product is not indicated for filling or core build-up.

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

7. Protect the product from extreme temperatures.

8. Avoid inhalation or digestion of material.

9. G-CEM ONE ADHESIVE ENHANCING PRIMER is volatile. Use in a well-ventilated area.

10. Do not mix with other products.

11. Light cure completely for an effective bonding. Lower light intensity may cause insufficient adhesion.

Some products referenced in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the safety data sheets available.

<http://sea.gcsidental.com>

They can also be obtained from your supplier.

CLEANING AND DISINFECTING

MULTI-USE PASTE PAK DISPENSER: To be cleaned and sterilized 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 healthcare-grade infection control product according to regional / national guidelines.

Terakhir direvisi: 01/2021

Last revised: 01/2021

Printed in Japan

Prior to use, carefully read the instructions for use.

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Sebelum digunakan, baca petunjuk penggunaan dengan seksama.

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G-CEM ONE™ Paste Pak
SELF-ADHESIVE RESIN CEMENT

G-CEM ONE™ ADHESIVE
ENHANCING PRIMER

TOOTH PRIMER FOR G-CEM ONE

Digunakan hanya untuk kalangan kedokteran gigi dengan indikasi yang disarankan.

INDIKASI UNTUK PENGUNAAN

1. Semua jenis inlay, onlay, mahkota, dan jembatan berbahan poroselain, resin dan logam.

2. Semua jenis veneer, pasak fiber dan komposit.