

INSTRUCTIONS FOR USE

INDICATION

Restoration where a light-curing composite for core build-up is required.

CONTRAINDICATION

Patients with a history of hypersensitivity reaction to methacrylate monomers.

INCOMPATIBILITY

Eugenol containing materials should not be used for pulp protection, root canal sealing and temporary filling since they retard the curing process.

PRECAUTIONS

[Safety precautions]

· Allergic hypersensitivity

- 1. Avoid use of the product for patients with a history of hypersensitivity to methacrylate-related
- Wear protective gloves or take other appropriate measures to prevent the occurrence of hypersensitivity due to contact with the product.
- If any hypersensitivity, such as a rash or dermatitis occurs, discontinue the use of the product and consult a physician.

· Contact with the human body

- Use caution to prevent the product from coming in contact with soft tissue or the skin, or getting into the
 eve.
- 2. If the product comes in contact with the human body, take the following measures: If the product gets in the eye, wash the eye immediately with copious amounts of running water and consult a physician. If the product comes in contact with the soft tissue or the skin, wipe it away with a cotton pledget or gauze moistened with alcohol and wash with copious amounts of water.
- 3. Use caution to prevent the patient from accidentally swallowing the product.
- 4. Avoid looking directly at the curing light when curing the product. Wear protective glasses.
- 5. Keep the product out of reach of children.

[Handling and manipulation precautions]

- 1. Use the composite within five (5) minutes after dispensing. Exposure to the operating light will cause the composite to cure.
- 2. The emitting tip of the visible light-curing activator should be held as near and vertical to the composite surface as possible. If a large composite surface is to be light cured, it is advisable to divide the area into several sections and light-cure each section separately.
- 3. Low intensity of light causes poor curing. Check the lamp for service life and the visible light guide tip for contamination. It is advisable to check the light intensity of light-curing activator using an appropriate light-checker at periodic intervals.

[Storage precautions]

- 1. Do not use after expiration date. Note expiration date on outside of package.
- 2. The product should be stored at room temperature (2-25°C/36-77°F)
- 3. Keep away from extreme heat or direct sunlight.
- 4. Replace the cap as soon as possible after the composite has been dispensed from the syringe.

CLINICAL PROCEDURES

A. CORE BUILD OF VITAL TOOTH

- 1. Cavity preparation
 - Determine the presence of caries and remove any infected dentin.
- 2. Drying the cavity
 - Rubber dam is recommended for isolation and moisture control.
- 3. Pulp protection
 - Generally there is no need for cement lining or basing. However, an actual or near pulp exposure should be covered with a hard setting calcium hydroxide material.
- 4. Applying a matrix strip and wedges
 - When necessary, apply a matrix strip and wedges
- Etching
- Apply K-ETCHANT GEL, etching agent, into the entire cavity surface with a sponge or disposable brush. After about 30 to 60 seconds, wash the etching agent away completely with water and dry with an air flow.
- Take care to prevent saliva from coming in contact with the etched tooth surface. Any contaminated tooth surface must be re-etched.
- 6. Applying the bonding agent
 - Mix one drop each of CLEARFIL NEW BOND Catalyst liquid and Universal liquid, and apply the mixture to the entire cavity surface with a sponge or disposable brush. Evaporate the ethanol of the mixture with a gentle air flow. (For detailed instructions, see the CLEARFIL NEW BOND instructions for use.)
- 7. Preparation of CLEARFIL PHOTO CORE
 - Dispense the necessary amount of the composite onto the paper pad by rotating the paste syringe plunger. After dispensing the composite, turn the plunger counter-clockwise a half- turn to prevent excess composite from oozing out.
 - Replace the syringe cap immediately to prevent premature setting of the composite.
- 8. Placing CLEARFIL PHOTO CORE into the cavity
- Place the composite into the cavity preparation using hand instruments. It is recommended that transparent matrix strips be used to help form the core.

Light-cure the composite with a dental visible light-curing activator. Hold the emitting tip as close to the composite as possible.

Irradiation should be continued for at least 30 seconds, and preferably 40 seconds or more as shown in the chart below.

Irradiation time	20sec.	40sec.	60sec.
Polymerization depth	5.5mm	7.0mm	8.0mm

10. Preparation of core

After the core sets, the matrix strip and wedges can be removed and the crown preparation started immediately.

B. CORE BUILD OF NON-VITAL TOOTH

1. Removal of soft dentine

Only carious dentine is removed, leaving as much healthy tooth structure as possible.

2. Endodontic treatment

Endodontic treatment is carried out according to the usual manner.

Eugenol containing root canal sealer should not be used since eugenol inhibits the polymerization of the resin material.

3. Preparation of the root canal

Prepare the root canal according to the usual manner.

4. Try-in of the post

A post of the proper diameter is fitted to the prepared root canal and the length of the post is adjusted. Posts must be sand blasted to provide roughened surface, and then cleaned for two-minutes in an ultrasonic cleaner, and dried.

5. Tooth surface treatment

Treat the tooth surface according to the PANAVIA instructions for use.

6. Preparation of dental adhesive cement

PANAVIA dental adhesive cement should be used for cementing the post.

7. Insertion of the post with PANAVIA paste

The sand blasted post should be cemented into the prepared canal with PANAVIA dental adhesive cement.

(For detailed instructions, see the PANAVIA instructions for use.)

8. Preparation of CLEARFIL PHOTO CORE

Dispense the necessary amount of CLEARFIL PHOTO CORE onto the paper pad by rotating the paste syringe plunger. After dispensing the composite, turn the plunger counter-clockwise a half-turn to prevent excess composite from oozing out.

Replace the syringe cap immediately to prevent premature setting of the composite.

9. Build-up of CLEARFIL PHOTO CORE

Using appropriate instruments, build-up the composite to the appropriate anatomy being careful to avoid incorporation of air bubbles.

When building-up an anterior tooth core, after the matrix strip or wedges are placed, the composite material is first placed around the post. Then, to avoid air bubbles, place additional increments of CLEARFIL PHOTO CORE while holding the matrix strip or wedges with finger pressure.

10. Light-cunno

Irradiate using a visible light-curing activator from at least two directions.

Irradiation should be continued for at least 30 seconds, and preferably 40 seconds or more as shown in the chart below.

Irradiation time	20sec.	40sec.	60sec.
Polymerization depth	5.5mm	7.0mm	8.0mm

11. Preparation of core

The cured composite has almost the same hardness as dentine, thereby providing a core build-up with cutting characteristics similar to that of dentin.

PRINCIPLE INGREDIENTS

Composite

Silanated glass powder

Silanated barium glass powder

Triethyleneglycol dimethacrylate

Bisphenol A diglycidylmethacrylate

dl-Camphorquinone

DELIVERY FORMS

3 syringe CLEARFIL PHOTO CORE, 4.4 g X 3

NOTE

CLEARFIL and PANAVIA are trademarks of KURARAY CO., LTD.

CAUTION

Federal(U.S.A.) law restricts this device to sale by or on the order of a licensed dentist.

WARRANTY

KURARAY CO., LTD. will replace any product that is proved to be defective. KURARAY CO., LTD. does not accept liability for any loss or damage, direct, consequential or special, arising out of the application or use of or the inability to use these products. Before using, the user shall determine the suitability of the products for the intended use and the user assumes all risk and liability whatsoever in connection therewith.