

ENGLISH INSTRUCTIONS FOR USE**I. INTRODUCTION**

CLEARFIL SA CEMENT is a dual-cure (light- and/or self-cure), self-adhesive resin cement for ceramic, hybrid ceramics (e.g. ESTENIA C&B), composite resin and metal restorations.

II. INDICATIONS

CLEARFIL SA CEMENT is indicated for the following uses.

- [1] Cementation of crowns, bridges, inlays and onlays made of ceramic, hybrid ceramics, composite resin or metal
- [2] Cementation of metal cores, resin cores, metal posts or glass fiber posts

III. CONTRAINDICATION

Patients with a history of hypersensitivity to methacrylate monomers.

IV. POSSIBLE SIDE EFFECT

The oral mucosal membrane may turn whitish when contacted by the product due to the coagulation of protein. This is a temporary occurrence that will usually disappear in a few days.

V. INCOMPATIBILITIES

- Do not use eugenol-containing materials for pulp protection or temporary sealing since the eugenol could retard the curing process.
- Do not use hemostatic agents containing ferric compounds, since these materials may impair adhesion and may cause discoloration at the tooth margin or surrounding gingiva due to ferric ions that may remain.
- Do not use a hydrogen peroxide solution for cleaning cavities because it might weaken the bond strength to the tooth structure.

VI. PRECAUTIONS**1. Safety precautions**

- Avoid using the product on patients with a known history of hypersensitivity to methacrylate monomers.
- If the patient demonstrates a hypersensitivity reaction, such as rash, eczema, features of inflammation, ulcer, swelling, itching or numbness, discontinue the use of the product and seek medical attention.
- Use caution when using the product to prevent contact with the soft oral tissue or skin. If the product comes in contact with the soft oral tissue or skin, wipe away with a cotton pledget moistened with alcohol and immediately rinse with copious amounts of water. Prior to use, cover the patient's eyes with a towel or safety glasses to protect from splashing materials. If the product gets in the eye, immediately rinse with copious amounts of water and consult an ophthalmologist.
- Use caution when using the product to prevent swallowing.
- Avoid direct contact with the skin and/or soft tissue to prevent hypersensitivity. Wear gloves or take appropriate precautions when using the product.
- Do not use the same mixing tip and endo tip for different patients to prevent cross contamination.

2. Handling and manipulation precautions

[Precautions when using the product]

- Do not use a lentulo spiral to insert the paste into the root canal; this can accelerate the polymerization of the paste beyond the desirable limits.
- Placing the prosthetic restoration should be completed within 40 seconds after the insertion of the paste into the cavity using an endo tip. Failure to do so will cause premature polymerization of the paste, due to the effects of temperature and/or water in the oral cavity.
- The paste contains a light cure catalyst that is highly photo-reactive. During cementation adjust the angle and/or distance of the dental light to reduce the intensity of light entering the oral cavity to prevent premature polymerization of the paste.
- Excess cement can be removed after tack light curing the excess for 2-5 seconds, or allowing the cement to self-cure for 3-5 minutes after placing the restoration. When removing the excess cement hold the restoration in place to avoid the possibility of lifting the restoration since there could be some insufficiently cured resin cement. If dental floss is used to remove the excess, it should be used in the direction that does not lift the prosthetic restoration.
- If the excess paste is removed from the margins before curing, light cure the margins of the prosthetic restoration to reduce the occurrence of any unpolymerized layer. For light curing time, refer to "A-6. Final Curing".
- If you want to place dental posts into several root canals of a posterior tooth, complete the post placement of one root

canal before proceeding with another, prevent the excess paste from entering another root canal.

- The product should stand for 15 minutes or more after it is removed from the refrigerator; this assures it is at room temperature and will restore the normal viscosity of the paste. In addition, this helps to prevent water contamination from possible refrigerator moisture.
- In multiple prosthetic restorations, complete the application of the cement to all the restorations within 1 minute of the initial dispensing. If application takes more than 1 minute, replace the first mixing tip or endo tip with a new one.
- After the dispensing into the mixing tip or endo tip, prevent the transparent part of it from exposure to strong light, such as the dental light; the paste inside it might harden from exposure to unnecessary light, leading to a shortened working time.

[Dental curing unit]

- Do not look directly at the light source. Protective glasses are recommended.
- If the curing unit light has low intensity, poor curing will result. Check the service life of the lamp and examine the emitting tip for contamination at periodic intervals. Also, it is advisable to check the time required to cure the paste by light curing a sample of the paste mix prior to starting the treatment.
- Check the conditions required to cure the paste mix by referring to the light-curing times listed in these Instructions for Use before using the product.
- The emitting tip of the dental curing unit should be held as near and vertical to the resin surface as possible. If a large resin surface is to be light cured, it is advisable to divide the area into several sections and light cure each section separately.

[Common precautions]

- Provide moisture control and use with a rubber dam.
- Any exposed pulp or areas near the pulp should be covered with a hard setting calcium hydroxide material.
- Clean the cavity sufficiently to prevent poor bonding. If the adherent surface is contaminated with saliva or blood, wash it thoroughly and dry before cementation.
- To prevent poor performance and handling characteristics, observe the specified light-curing times and other handling requirements.
- Do not mix the product with any other dental material.
- Be careful not to cut your fingers on the sharp edges of the instruments.
- Do not use the product for any other purposes other than those specified in INDICATIONS.
- The use of this product is restricted to licensed dentist.

3. Storage precautions

- The product should be used by the expiration date indicated on the package.
- The product should be stored in a refrigerator (2 - 8°C/36 - 46°F) when not use.
- Keep away from extreme heat or direct sunlight.
- The product should be carefully stored and used by a licensed dental professional.

VII. COMPONENTS

Please see the outside of the package for contents and quantity.

1) PASTE A and B : Universal (A2), White

Principal ingredients

(1) PASTE A

- Bis phenol A diglycidylmethacrylate (Bis-GMA)
- Triethyleneglycol dimethacrylate (TEGDMA)
- 10-Methacryloyloxydecyl dihydrogen phosphate (MDP)
- Hydrophobic aromatic dimethacrylate
- Silanated barium glass filler
- Silanated colloidal silica
- dl-Camphorquinone
- Benzoyl peroxide
- Initiator

(2) PASTE B

- Bis phenol A diglycidylmethacrylate (Bis-GMA)
- Hydrophobic aromatic dimethacrylate
- Hydrophobic aliphatic dimethacrylate
- Silanated barium glass filler
- Silanated colloidal silica
- Surface treated sodium fluoride
- Accelerators

- Pigments

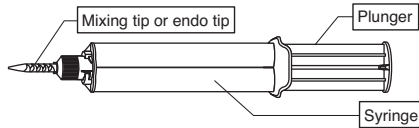
The total amount of inorganic filler is approx. 45vol% (66wt%). The mean particle size is 2.5µm.

- 2) Accessories
- Mixing tip
 - Endo tip

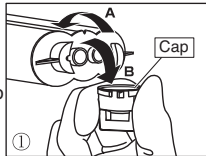
VIII. CLINICAL PROCEDURES

SYRINGE PREPARATION

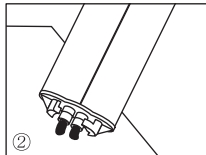
Device components.



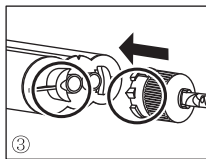
1. Turn the cap 1/4 of a turn counterclockwise to align the projections on the cap with the grooves (A) in the syringe. Holding the base of the cap, remove the cap by twisting and pressing downward (B).



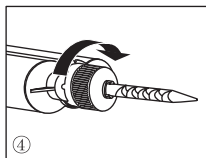
2. Squeeze out small amounts of the two pastes, making sure equal amounts are being dispensed through the two outlets of the syringe. For the next and all subsequent uses, make sure equal amounts of the two pastes are being dispensed. If equal amounts of paste are not used, there is a possibility of poor polymerization.



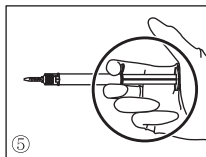
3. Attach a mixing tip or an endo tip to the syringe aligning the projections on it with the grooves in the syringe as closely as possible.



4. Turn the mixing tip or the endo tip 1/4 of a turn clockwise and lock it in place.



5. The mixed pastes will be dispensed when the plunger is pressed.



[NOTE]

- After use, the syringe should be stored with either the cap or the mixing tip or the endo tip attached. The next time the syringe is used, replace the old one with a new one. (If you put the cap back on the syringe before storage, make sure the cap is free of paste.)
- When replacing an old mixing tip and endo tip with a new one, turn it 1/4 of a turn counterclockwise to align the projections of the mixing tip or the endo tip with the grooves in the syringe. Remove it from the syringe by twisting and pressing downward.
- If the paste has hardened making it difficult to squeeze the paste mixture out of the syringe, remove hardened paste by using an appropriate instrument.
- When changing the direction of the endo tip, do not move by the dispensing part of the endo tip.

A. Indications 1

- [1] Cementation of crowns, bridges, inlays and onlays made of ceramic, hybrid ceramics, composite resin or metal

The following flow chart shows the standard clinical procedure for cementing a crown

Conditioning the cavity and abutment surfaces

- ▼ Clean and dry the cavity and abutment surfaces, and then trial fit the prosthetic restoration.

Conditioning the prosthetic restoration surface

- ▼ Sandblast, then ultrasonic clean and dry. (If the restoration surface is made from conventional silica-based ceramic, apply a phosphoric acid and a silane coupling agent according to its the Instructions for Use.)

Preparing the syringe and accessories

- ▼ Set the mixing tip on the syringe.

Cementing the prosthetic restoration

- ▼ Apply the cement paste mix to the restoration and place on the abutment.

Removing the excess cement

- ▼ Light cure for 2 to 5 seconds or chemical cure for 3 to 5 minutes, then remove the excess cement.

Final curing

Maintain isolation for 5 minutes.

A-1. Conditioning the cavity and abutment surfaces

- (1) Remove the temporary sealing material and temporary cement in the usual manner, and clean the cavity and provide moisture control.
- (2) Trial fit the prosthetic restoration to check the fit of the restoration in the cavity or the abutment.

A-2. Conditioning the prosthetic restoration surface

Condition the prosthetic restoration surface as follows:

If the adherent surface is metal, metal oxide ceramic such as zirconia, hybrid ceramic or composite resin

Roughen the adherent surface by sand blasting with 30 to 50 µm alumina powder at an air pressure of 0.1 - 0.4MPa (1-4kg / cm²). The air pressure should be properly adjusted to suit the material and/or shape of the prosthetic restoration, using caution to prevent chipping. After sand blasting, clean the prosthetic restoration by using ultrasound for 2 minutes followed by drying it with an air stream.

If the adherent surface is conventional silica-based ceramic

Apply a phosphoric acid (e.g. K-ETCHANT GEL) over the adherent surface, leave it for 5 seconds, then wash and dry the surface. Then, apply a silane coupling agent (e.g. CLEARFIL CERAMIC PRIMER) according to the Instructions for Use.

A-3. Preparing the syringe and accessories

Prepare the syringe and accessories according to "SYRINGE PREPARATION."

CLEARFIL DISPENSER (5ml, 1:1) can be used for easy dispensing. For detailed descriptions, refer to the Instructions for Use supplied with the CLEARFIL DISPENSER.

A-4. Cementing the prosthetic restoration

- (1) Use the mixing tip to apply the cement paste mix over the entire adherent surface of the prosthetic restoration or the entire tooth surface within the cavity. If the paste is applied into the cavity using the endo tip, you must start step (2) within 40 seconds after application of the cement.
- (2) Place the prosthetic restoration into the cavity or on the abutment.

[CAUTION]

When using the dispensing syringe, be careful to avoid cross infection. Cover the entire syringe with something like a poly bag to prevent saliva and blood from contacting the syringe. Also disinfect the syringe, mixing tip, and endo tip by wiping them well with an absorbent cotton having some alcohol before and after using.

A-5. Removing the excess cement

Remove any excess cement using either of the following two methods:

Light curing

Light cure any excess cement for 2 to 5 seconds at several spots. Holding the prosthetic restoration in position, remove the semi-cured excess cement using a dental explorer instrument. It is advisable to determine in advance the light curing time of the excess cement by light curing some paste on a mixing paper.

Chemical curing

Leave any excess cement for 3 to 5 minutes after placement of the prosthetic restoration. Remove the semi-cured excess cement using a dental explorer instrument.

A-6. Final curing

Finally, cure the cement using either of the following two methods:

Prosthetic restorations that are not translucent (e.g. metal crowns):

Allow the cement to chemical cure by letting it rest for 5 minutes after placement of the prosthetic restoration.

Prosthetic restorations that are translucent (e.g. ceramic inlays):

Light cure the entire surface and margins of the prosthetic restoration following the table below.

Table: Dental curing unit

Type	Light source	Wavelength range and light intensity
Conventional halogen	Halogen lamp	Light intensity ²⁾ of 300 - 550 mW/cm ² in wavelength range from 400 - 515 nm
Fast halogen	Halogen lamp	Light intensity ²⁾ of more than 550 mW/cm ² in wavelength range from 400 - 515 nm
Plasma arc	Xenon lamp	Light intensity ³⁾ of more than 2000 mW/cm ² in wavelength range from 400 - 515 nm, and light intensity of more than 450 mW/cm ² in wavelength range from 400 - 430 nm.
LED	Blue LED ¹⁾	Light intensity ²⁾ of more than 300 mW/cm ² in wavelength range from 400 - 515 nm

1) Peak of emission spectrum: 450 - 480 nm.

2) Evaluated according to ISO 10650-1.

3) Wavelength distribution and light intensity values measured with a spectro-radiometer calibrated using an IEC or the NIST (National Institute of Standards and Technology) standard lamp.

Table: Light curing time

Dental curing unit	Light curing time
Conventional halogen	20 seconds
LED	
Fast halogen	5 seconds
Plasma arc	

If the area you want to light cure is larger than the light emitting tip, divide the exposure process into a few applications.

B. Indications 2

[2] Cementation of metal cores, resin cores, metal posts or glass-fiber posts

The following flow chart shows the standard clinical procedure for post cementation.

<u>Preparing a cavity and trial fitting the post</u> ▼ Clean and dry the prepared cavity, and then trial fit the post.
<u>Sand blasting the post (if necessary)</u> ▼
<u>Preparing the syringe and accessories</u> ▼ Set the endo tip to the syringe.
<u>Placing the post</u> ▼ Apply the cement paste mix to the cavity. Place the post into the cavity.
<u>Removing the excess cement</u> ▼ Light cure for 2 to 5 seconds or chemical cure for 3 to 5 minutes, then remove the excess cement.
<u>Light curing</u> ▼ Light-cure the cement for 20 sec.
<u>Core build-up</u> Apply a bonding agent and load a core build-up composite resin according its Instructions for Use.

B-1. Preparing a cavity and trial fit the core or post

- (1) Prepare the endodontically filled root canals for post / core placement in the usual manner. Provide moisture control with a rubber dam.
- (2) Trial fit a core or a dental post of appropriate length and thickness in the prepared cavity. Cut and trim the post as necessary. Wipe away any contamination from the surface of the core or post using a piece of gauze or a cotton pad soaked with ethanol.

B-2. Sand blasting the core or post

Sandblast the core or post surface according to step "A-2. Conditioning the prosthetic restoration surface." Do not sandblast glass fiber posts, because it might damage the glass fiber post.

B-3. Preparing the syringe and accessories

Prepare the syringe and accessories according to "SYRINGE PREPARATION."

CLEARFIL DISPENSER (5ml, 1:1) can be used for easy dispensing. For detailed descriptions, refer to the Instructions for Use supplied with the CLEARFIL DISPENSER.

B-4. Placing the core or post

- (1) Use the mixing tip to apply the cement paste mix over the entire adherent surface of the core or post, or use the endo tip to load the cement paste mix into the cavity. If the paste is applied into the cavity using the endo tip, you must start step (2) within 40 seconds after application of the cement.
- (2) Place the core or post quickly into the cavity, slightly vibrating it to prevent air bubbles from entering the root canals.

[CAUTION]

When using the dispensing syringe, be careful to avoid cross infection. Cover the entire syringe with something like a poly bag to prevent saliva and blood from contacting the syringe. Also disinfect the syringe, mixing tip, and endo tip by wiping them well with an absorbent cotton having some alcohol before and after using.

B-5. Removing the excess cement

Remove any excess cement using either of the following two methods:

Light curing

Light cure any excess cement for 2 to 5 seconds at each spot. Remove the semi-cured excess cement using a dental explorer instrument.

Chemical curing

Leave any excess cement for 3 to 5 minutes. Remove the semi-cured excess cement using a dental explorer instrument.

B-6. Light curing

Light cure margins of the core or post, according to the table "Light curing time" in A-6, for the specified length of time.

B-7. Preparing for the final restoration

For cores

Seat the core in place for about 10 minutes and make sure the cement has been completely cured before preparing the abutment tooth.

For dental posts

After placing the dental post, apply the bonding agent (e.g. CLEARFIL DC BOND, CLEARFIL LINERBOND 2V) and load the core build-up composite resin (e.g. CLEARFIL DC CORE AUTOMIX, CLEARFIL PHOTO CORE, or CLEARFIL CORE) according to its Instructions for Use.

[WARRANTY]

KURARAY MEDICAL INC. will replace any product that is proved to be defective. KURARAY MEDICAL INC. 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.

[NOTE]

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