

CLEARFILTM ***PHOTO BOND***

ENGLISH INSTRUCTIONS FOR USE

CLEARFIL PHOTO BOND is a dual curing dentin and enamel bonding agent developed for use with composite light-curing restorative materials.

INDICATION

Enamel and dentin bonding agent for direct composite restorations.

CONTRAINDICATION

Patients with a history of hypersensitivity to methacrylate monomers.

INCOMPATIBILITY

Eugenol containing materials should not be used for pulp protection 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 monomers.
2. Wear protective gloves or take other appropriate measures to prevent the occurrence of hypersensitivity due to contact with the product.
3. 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

1. Use caution to prevent the product from coming in contact with soft tissue or the skin, or getting into the eye.
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 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 material.

Others

1. Note that this product is flammable. Do not use or store it near open flames.

[Handling and manipulation precautions]

1. Use CLEARFIL PHOTO BOND within two (2) minutes after mixing.
2. Exposure to the operating light will allow the mixture of CLEARFIL PHOTO BOND to cure.
3. The emitting tip of the visible light-curing activator should be held as near and vertical to the cavity surface as possible. If a large cavity surface is to be light-cured, it is advisable to divide the area into several sections and light-cure each section separately.
4. Low intensity of light causes poor adhesion. 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 refrigerated when not in use; bring it to room temperature before using.
3. Keep away from extreme heat or direct sunlight.
4. Replace the bottle cap as soon as possible after bonding agent has been dispensed from the bottle.

CLINICAL PROCEDURES

1. Moisture control

To attain proper adhesion the preparation site should be kept dry. For this purpose, the use of rubber-dam is recommended.

2. Cavity preparation

First clean the tooth surface with pumice and wash thoroughly with water. Then, remove all infected tooth structure and prepare the cavity conservatively. Determine the presence of caries and remove any infected dentin. Generally there is no need for cement lining or basing. However, any actual or near pulp exposure should be covered

with calcium hydroxides.

3. Etching

Dispense one drop of K-ETCHANT GEL into a well of mixing dish and apply it to the entire cavity surface with a small brush. After 15 to 30 seconds, wash thoroughly and dry with an air syringe. Care should be taken to prevent saliva from coming in contact with the etched tooth surface. Any contaminated tooth surface must be re-etched.

4. Mixing of CLEARFIL PHOTO BOND

Carefully dispense one drop of the Catalyst liquid into a well of mixing plate. To this Catalyst drop add one drop of the Universal liquid. Stir the two liquids quickly with a sponge or disposable brush. The mixed CLEARFIL PHOTO BOND must then be applied to the etched cavity surface within two minutes.

5. Application of CLEARFIL PHOTO BOND

Apply CLEARFIL PHOTO BOND to the entire cavity surface with a sponge or disposable brush. Carefully spread the bonding agent over the surface of the cavity with a gentle air flow for 2 or 3 seconds. In this way the volatile substances evaporate and a thin film of bonding agent is formed which does not harden as long as it is in contact with oxygen.

6. Polymerization of CLEARFIL PHOTO BOND

Polymerize CLEARFIL PHOTO BOND by irradiation using a visible light-curing activator for 10 seconds. If the thickness of light-curing composite is less than 2 mm, CLEARFIL PHOTO BOND need not be polymerized before placement of the composite.

7. Application of composite

Place a light-curing composite into the cavity within one minute after applying CLEARFIL PHOTO BOND, polymerize, and finish according to the manufacturers instructions for use.

COMPONENTS

K-ETCHANT GEL : 1 bottle (6ml)

CLEARFIL PHOTO BOND :

Catalyst liquid, 1bottle (6ml)

Universal liquid, 1 bottle (6ml)

Each component is available as a refill.

PRINCIPLE INGREDIENTS

K-ETCHANT GEL

Phosphoric acid

Colloidal silica

Water

CLEARFIL PHOTO BOND

Catalyst liquid

Bisphenol A diglycidylmethacrylate
10-Methacryloyloxydecyl dihydrogen phosphate
2-hydroxyethyl methacrylate
Hydrophobic dimethacrylate
Benzoyl peroxide
dl-Camphorquinone

Universal liquid

N, N'-Diethanol p-toluidine
Sodium benzen sulfinate
Ethyl alcohol

CAUTION

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

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

CLEARFIL is a trademark of KURARAY CO., LTD.

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