

# ADHESIVE RESIN CEMENT SYSTEM PANAVIA<sup>TM</sup> V5

## ENGLISH INSTRUCTIONS FOR USE

### I. INTRODUCTION

PANAVIA V5 is an adhesive resin cement system. PANAVIA V5 consists of the cement paste (Paste) and the K-ETCHANT Syringe. CLEARFIL CERAMIC PRIMER PLUS and K-ETCHANT Syringe. The Paste is a dual-cure gel (endovisual and self-cure), fluoride-releasing, radiopaque resin cement for ceramics (lithium disilicate, ceramic delivery system), hybrid ceramics, composite resins, and metal restorations. It is supplied in an autometrix system which mixes equal amounts of two components. It is available in the following 5 shades: Universal (A2), Clear, Brown (A4), White, and Opaque. The Opaque shade should be self-cured for final curing due to its strong opacity. The Try-in Paste is a shade matching material which has approximate color and transparency as the hardened mixture of Paste. CLEARFIL CERAMIC PRIMER PLUS is a dental universal prosthetic primer that provides an enhanced adhesive surface to ceramics, hybrid ceramics, composite resins and metals. K-ETCHANT Syringe is an etching gel that consists of 35% phosphoric acid aqueous solution and colloidal silica.

### II. INDICATIONS

PANAVIA V5 is indicated for the following uses:

- [1] Cementation of crowns, bridges, inlays and onlays
- [2] Cementation of veneers
- [3] Cementation of adhesion bridges and splints
- [4] Cementation of prosthetic restorations on implant abutments and frames
- [5] Cementation of posts and cores
- [6] Amalgam bonding

### III. CONTRAINDICATIONS

Patients with a history of hypersensitivity to methacrylate monomers

### IV. POSSIBLE SIDE EFFECTS

[1] The product may turn white when contacted by the product due to the coagulation of protein. This is usually a temporary phenomenon that will disappear in a few days. Instruct patients to avoid irritating the affected area while brushing.

[2] K-ETCHANT Syringe may cause inflammation or erosion due to its chemistry. Use caution to prevent the product from coming in contact with the skin or getting into the eye.

### V. INCOMPATIBILITIES

[1] Do not use eugenol-containing materials for pulp protection or temporary sealing, since the eugenol can retard the curing process.

[2] Do not use hemostatics containing ferric compounds since these materials may impair adhesion and may cause discoloration of the tooth margin or surrounding gingiva due to remaining ferric ions.

[3] Do not use a hydrogen peroxide solution for cleaning cavities since it may weaken the bond strength to the tooth structure.

### VI. PRECAUTIONS

**1. Safety precautions**

- 1. The product contains substances that may cause allergic reactions. Avoid use of the product in patients with known allergies to methacrylate monomers or any other components.
- 2. If the patient demonstrates a hypersensitivity reaction, such as rash, eczema, features of inflammation, ulcer, swelling, itching or numbness, discontinue use of the product and seek medical attention.
- 3. Avoid direct contact with the skin and/or soft tissue to prevent hypersensitivity. Wear gloves or take appropriate precautions when using the product.
- 4. Exercise caution to prevent the product from coming in contact with the skin or getting into the eye. Before applying the product, wash the patient's eyes with a towel or soft glasses to protect them in the event of splashing material.
- 5. If the product comes in contact with human body tissues, take the following actions:
  - <If the product gets in the eye> Immediately wash the eye with copious amounts of water and consult a physician.
  - <If the product comes in contact with the skin or the oral mucosa> Immediately wipe the area with a cotton pellet or a gauze pad moistened with alcohol, and rinse with copious amounts of water.
- 6. Exercise caution to prevent patient from accidentally swallowing the product.
- 7. Do not reuse the mixing tip, the endo tip, the needle tip and the applicator brush to prevent cross-contamination. These are single-use and should be discarded after use.

### 2. Handling and manipulation precautions

**[Common precautions]**

- 1. The product must not be used for any purposes other than specified in [ INDICATIONS].
- 2. The use of this product is restricted to dental professionals.
- 3. Do not use the product as a provisional cement. This material is designed to use as a permanent cement.
- 4. Use a rubber dam to prevent contamination and to control moisture.
- 5. Use a pulp capping agent in a cavity close to the pulp or in the event of accidental pulp exposure.
- 6. When using hemostatics containing aluminum chloride, minimize its quantity, and use caution to prevent contact with the adherent surface. Failure to do so might weaken the bond strength to the tooth structure.
- 7. Completely remove any living materials, amalgam and temporary sealing material when preparing the tooth to avoid over saturation.
- 8. Do not mix the product with any other dental materials.
- 9. If the containers and/or instruments for this product are damaged, protect yourself from any danger and immediately discontinue their use.
- 10. Do not use the same applicator brush for both the Tooth Primer and CLEARFIL CERAMIC PRIMER PLUS.

**[Paste]**

- 1. The Opaque shade should be self-cured for final curing due to its low curing depth. The margins of the prosthetic restoration can be light-cured.
- 2. The Paste must be used within 2 minutes after dispensing.
- 3. The polymerization of the paste will be accelerated by contact with Tooth Primer. The procedure should be carried out within the working time listed in the table below.
- The Paste must be applied only to one veneer at a time when cementing multiple veneers.

Paste setting time in the oral cavity (at 37°, after coming into contact with Tooth Primer)

Working time	60 seconds
Setting time	3 minutes

4. Be careful to prevent unnecessary exposure to direct sunlight or operating lights. 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.

5. Do not use a Lentulo spiral to insert the paste into the root canal.

6. If you want to place dental posts into several root canals of one tooth, complete the post placement in each root canal sequentially, one at a time, before proceeding with another. Make sure to prevent the excess cement from entering another root canal.

7. When dispensing the cement intra-orally using the mixing tip or endo tip, be careful to avoid cross-contamination. Cover the entire syringe with a disposable plastic barrier to prevent saliva and blood contamination. Disinfect the syringe by wiping it with an absorbent cotton with alcohol both before and after use.

8. Excess cement can be removed after tack light-curing it for 3-5 seconds. 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.

**[Try-in Paste]**

- 1. The use of the Try-in Paste should be limited to checking the shade matching with the PANAVIA V5 Paste.
- 2. The Try-in Paste does not set. Do not use it to cement restorations.
- 3. A transparent liquid may appear at the tip of the Try-in Paste syringe. If this transparent liquid is present, it should be dispensed and discarded, since the separated liquid may affect the shade matching.
- 4. Shade evaluation with Try-in Paste should be performed using the same approximate thickness of Try-in Paste as the hardened cement.
- 5. After use, thoroughly wash the Try-in Paste from the restoration and tooth surface with water to avoid poor adhesion.

**[Tooth Primer]**

- 1. Use within 5 minutes after dispensing.
- 2. Do not use for surface treatment of implant abutments, frames and prosthetic restorations (inlays, onlays, crowns, bridges and splints). The polymerization of the paste will be accelerated at the working time will not be sufficient.

3. Only use with PANAVIA V5 Paste. Do not use in conjunction with other resin cement (e.g. PANAVIA F 2.0 or CLEARFIL ESTHETIC CEMENT EX).

4. Clean the cavity sufficiently to prevent poor bonding. If the adherent surface is contaminated with saliva or blood, wash it thoroughly and dry. Then re-apply the Tooth Primer.

**[CLEARFIL CERAMIC PRIMER PLUS]**

- 1. CLEARFIL CERAMIC PRIMER PLUS should be used shortly after dispensing. CLEARFIL CERAMIC PRIMER PLUS contains volatile ethanol. As the solvent evaporates, the viscosity increases and may make it difficult to apply.

2. Perform bonding (or cementation) soon after treating the restoration surface with CLEARFIL CERAMIC PRIMER PLUS.

3. If the treated surface is contaminated with saliva or blood, wash it with water, dry, clean with K-ETCHANT Syringe and re-treat.

**[K-ETCHANT Syringe]**

- 1. Be careful not to contaminate it with saliva or blood. If the treated surface is contaminated, re-treat.
- 2. Be careful to avoid cross-contamination. Disinfect the syringe by wiping it with an absorbent cotton with alcohol both before and after use. Cover the entire syringe with a disposable plastic barrier to prevent saliva and blood contamination.

3. If the product adheres to clothing, wash it off with water.

4. After each use, remove the needle tip from the syringe and recap the syringe immediately and tightly.

5. Etching the vital dentin may cause post-operative sensitivity.

### Dental light-curing unit

1. Use it according to the instructions for use for the dental light-curing unit.

2. Do not look directly at the light source. Protective glasses are recommended.

3. Low light intensity causes poor adhesion. Check the lamp for service life and the dental curing light guide tip for contamination. It is advisable to check the dental curing light intensity using an appropriate light-curing device and dental light-curing units.

4. The angle and height of the dental curing device and dental light-curing units should be parallel and vertical to the resin surface as possible. If a large resin surface has to be light-cured, it is advisable to divide the area into several sections and light-cure each section separately.

5. Check the conditions required to cure the paste mixture by referring to the light-curing times listed in these Instructions for Use before using the product.

### Storage precautions

1. The product must be used by the expiration date indicated on the package.

2. The product must be stored in a cool, dry place (temperature range: 2-8°C / 36-46°F) when not in use, and should be brought to room temperature for 15 minutes before use in order to restore its normal viscosity and curing properties. Try-in Paste and K-ETCHANT Syringe should be stored at 2-25°C/36-77°F when not in use.

3. The product must be kept away from extreme heat, direct sunlight or a flame.

4. The bottle or syringe cap should be replaced as soon as the liquid or paste has been dispensed from the bottle or syringe. This prevents evaporation of volatile ingredients.

5. The product must be stored in a proper place where only dental practitioners can access.

### VII. COMPONENTS

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

**Principal ingredients:**

1) Paste: Universal (A2), Clear, Brown (A4), White, Opaque

- Bisphenol A diglycidylmethacrylate (Bis-GMA)
- Triethyleneglycol dimethacrylate (TEGDMA)
- Hydrophilic aromatic dimethacrylate
- Hydrophilic aliphatic dimethacrylate
- Initiators
- Accelerators
- Silanated barium glass filler
- Silanated fluoromalinocarbonate glass filler
- Colloidal silica

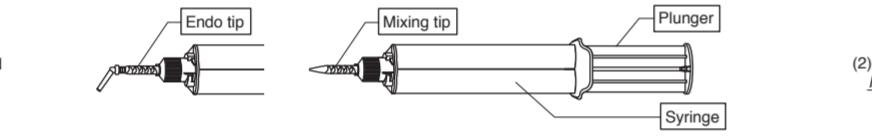
### (2) Paste B

- Bisphenol A diglycidylmethacrylate (Bis-GMA)
- Hydrophilic aromatic dimethacrylate
- Hydrophilic aliphatic dimethacrylate
- Silanated barium glass filler
- Silanated aluminum oxide filler
- Accelerators
- di-Camphorquinone
- Pigments

The total amount of inorganic filler is approximately 38 vol%.

The particle size of organic fillers range from 0.01 µm to 12 µm.

### Device components:



### 2) Try-in Paste: Universal (A2), Clear, Brown (A4), White, Opaque

- Glycerol
- Silanated silica
- Silanated colloidal silica
- Colloidal silica
- Pigments

The total amount of inorganic filler is approximately 38 vol%.

The particle size of organic fillers range from 0.01 µm to 12 µm.

### 3) K-ETCHANT Syringe

- Hydrochloric acid
- Water
- Colloidal Silica
- Pigment

5) CLEARFIL CERAMIC PRIMER PLUS

- 3-Methacryloyloxypropyl trimethoxysilane
- 10-Methacryloyloxydecyl dihydrogen phosphate (MDP)
- 2-Hydroxyethyl methacrylate (HEMA)
- Hydrophilic aliphatic dimethacrylate
- Accelerators
- Water

### 6) Accessories

- Mixing tip
- Endo tip (S)
- Needle tip (E) (for K-ETCHANT Syringe)
- Applicator brush (fine <silver>)
- Mixing dish

### VIII. CLINICAL PROCEDURES

#### A. Standard procedure I (Indications [1], [2] and [3])

[1] Cementation of crowns, bridges, inlays and onlays

[2] Cementation of veneers

[3] Cementation of adhesion bridges and splints

#### A-1. Cleaning the prepared tooth (tooth, metal, composite resin)

When cementing to the prepared tooth, remove the temporary sealing material and temporary cement in the usual manner; clean the cavity using moisture control.

3. Avoid direct contact with the skin and/or soft tissue to prevent hypersensitivity. Wear gloves or take appropriate precautions when using the product.

4. Exercise caution to prevent the product from coming in contact with the skin or getting into the eye. Before applying the product, wash the patient's eyes with a towel or soft glasses to protect them in the event of splashing material.

5. If the product comes in contact with human body tissues, take the following actions:
 

- <If the product gets in the eye> Immediately wash the eye with copious amounts of water and consult a physician.
- <If the product comes in contact with the skin or the oral mucosa> Immediately wipe the area with a cotton pellet or a gauze pad moistened with alcohol, and rinse with copious amounts of water.

6. Exercise caution to prevent patient from accidentally swallowing the product.

7. Do not reuse the mixing tip, the endo tip, the needle tip and the applicator brush to prevent cross-contamination. These are single-use and should be discarded after use.

**B. Application of CLEARFIL CERAMIC PRIMER PLUS to the prosthetic restoration surface**

Please follow the Instructions for Use of the restorative material. In the absence of specific instructions, we recommend the following procedures and application of CLEARFIL CERAMIC PRIMER PLUS:

**If the adherent surface is metal oxide ceramic (e.g. KATANA Zirconia) or metal:**

(1) Roughen the adherent surface by blasting with alumina powder (30-50 µm) using air pressure of 0.1-0.4 MPa (1-4 kg/cm<sup>2</sup>, 15-58 psi). The air pressure and powder size should be properly adjusted to suit the material and/or shape of the prosthetic restoration, using caution to prevent chipping.

(2) Clean the prosthetic restoration in an ultrasonic cleaning unit for 2 minutes followed by drying it with an air stream.

**If the adherent surface is silica-based ceramic (e.g. conventional porcelain, lithium disilicate), hybrid ceramics or composite resin:**

Based on the type of restorative, Acid Treatment or Blasting Treatment may be used:

**Acid Treatment (e.g. conventional porcelain, lithium disilicate):**

(1) Etch the adherent surface with a hydrofluoric acid solution in accordance with the Instructions for Use of the restorative material, or apply K-ETCHANT Syringe over the adherent surface and leave it for 5 seconds.

(2) Clean the adherent surface with water and dry.

**Blasting Treatment (e.g. composite resin):**

(1) Roughen the adherent surface by blasting with alumina powder (30-50 µm) using air pressure of 0.1-0.2 MPa (1-2 kg/cm<sup>2</sup>, 15-29 psi). The air pressure and powder size should be properly adjusted to suit the material and/or shape of the prosthetic restoration, using caution to prevent chipping.

(2) Clean the prosthetic restoration in an ultrasonic cleaning unit for 2 minutes followed by drying it with an air stream.

**C. Application of CLEARFIL CERAMIC PRIMER PLUS to the prosthetic restoration**

(1) If the adherent surface is composite resin, apply K-ETCHANT Syringe onto the adherent surface and leave it for 5 seconds; rinse and dry.

(2) Apply CLEARFIL CERAMIC PRIMER PLUS to the adherent surface of the restoration with an applicator brush. After application, dry the entire adherent surface sufficiently using mild, oil-free air.

**D. Application of Tooth Primer to the prepared tooth**

Based on the type of adherent surface and/or procedure, treat as follows before application of Tooth Primer.

**Etching of the enamel surface (Optional, but necessary for veneers and adhesive bridges):**

A clinically adequate adhesive bond is achieved by the application of Tooth Primer without an extra phosphoric acid etching step.

If the adherent surface is uncut enamel or when cementing an adhesion bridge or veneers, apply K-ETCHANT Syringe to the enamel surface only and leave for 10 seconds; rinse and dry.

**Treatment of the prepared tooth**

Apply ALLOY PRIMER according to the Instructions for Use.

**Table 1: Setting time for type of light source**

Type of light source (Light intensity) Curing time

