



033 1562588R

ADHESIVE RESIN CEMENT SYSTEM

PANAVIA™ V5

[ENGLISH] INSTRUCTIONS FOR USE

I. INTRODUCTION

PANAVIA V5 is an adhesive resin cement system. PANAVIA V5 consists of the cement paste (Paste), Try-In Paste, Tooth Primer, CLEARFIL CERAMIC PRIMER PLUS and K-ETCHANT Syringe. The Paste is a dual-cure (light- and/or self-cure), fluoride-releasing, radiopaque resin cement for ceramics (lithium disilicate, zirconia, etc.), hybrid ceramics, composite resins, and metal restorations. It is supplied in an automatic delivery 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. The Tooth Primer is a self-etching primer to tooth structure that accelerates the polymerization of the Paste. CLEARFIL CERAMIC PRIMER PLUS is a dental restorative 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:

- Cementation of crowns, bridges, inlays and onlays
- Cementation of veneers
- Cementation of adhesion bridges and splints
- Cementation of prosthetic restorations on implant abutments and frames
- Cementation of posts and cores
- Amalgam bonding

III. CONTRAINDICATIONS

Patients with a history of hypersensitivity to methacrylate monomers

IV. POSSIBLE SIDE EFFECTS

- If the oral mucosal membrane may turn whitish 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.
- 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

- Do not use eugenol-containing materials for pulp protection or temporary sealing, since the eugenol may cause discoloration and can retard the curing process.
- Do not use hemostatic agents containing ferric compounds since these materials may impair adhesion and may cause discoloration of the tooth margins or surrounding gingiva due to remaining ferric ions.
- 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

- This product contains substances that may cause allergic reactions. Avoid use of the product on patients with known allergies to methacrylate monomers or any other components.
- If the patient demonstrates a hypersensitivity reaction, such as rash, eczema, features of inflammation, odor, swelling, itching or numbness, discontinue use of the product and seek medical attention.
- Avoid direct contact with the skin and/or soft tissue to prevent hypersensitivity. Wear gloves or take appropriate precautions when using the product.
- Exercise caution to prevent the product from coming in contact with the skin or getting into the eye. Before using the product, cover the patient's eyes with a towel or safety glasses to protect them in the event of splashing material.
- If the product comes in contact with human body tissues, take the following actions:
 - <If the product gets in the eyes>
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.
- Exercise caution to prevent the patient from accidentally swallowing the product.
- Do not reuse the mixing tip, the end tip, the needle tip and the applicator brush to prevent cross-contamination. These are single-use and should be discarded after using.

2. Handling and manipulation precautions

[Common precautions]

- The product must not be used for any purposes other than specified in [.INDICATIONS].
- The use of this product is restricted to dental professionals.
- Do not use the product as a provisional cement. This material is designed to use as a permanent cement.
- Use a rubber dam to prevent contamination and to control moisture.
- Use a pulp capping agent in a cavity close to the pulp or in the event of accidental pulp exposure.
- When using temporary materials containing tannin or magnesia, completely remove it after preventing the discoloration.
- When using hemostatic agents 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.
- Completely remove any lining materials, amalgam and temporary sealing materials when preparing the cavity to avoid poor adhesion.
- Do not mix the product with any other dental materials.
- If the containders and/or instruments for this product are damaged, protect yourself from any danger and immediately discontinue their use.
- Do not use the same applicator brush for both the Tooth Primer and CLEARFIL CERAMIC PRIMER PLUS.

[Paste]

- 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.
- The Paste must be used within 2 minutes after dispensing.
- 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 °C after coming into contact with Tooth Primer)

Working time	60 seconds
Setting time	3 minutes

- 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 avoid premature polymerization of the Paste.
- Do not use a LentoLulo spiral to insert the paste into the root canal.
- If you want to place dental posts into several root canals of one tooth, complete the post placement of one root canal before proceeding with another. Make sure to prevent the excess cement from entering another root canal.
- When dispensing the cement intra-orally using the mixing tip or end 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.
- 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]

- The use of the Try-in Paste should be limited to checking the shade matching with the PANAVIA V5 Paste.
- The Try-in Paste does not set. Do not use it to cement restorations.
- 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.
- Shade evaluation with Try-in Paste should be performed using the same approximate thickness of Try-in Paste as the hardened cement.
- After use, thoroughly wash the Try-in Paste from the restoration and tooth surface with water to avoid poor adhesion.

[Tooth Primer]

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

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

- Be careful not to contaminate it with saliva or blood. If the treated surface is contaminated, re-treat.

A-4. 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 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 flow.

[NOTE]

For optimal performance, ALLOY PRIMER can be used on the surface of the precious metal alloy instead of CLEARFIL CERAMIC PRIMER PLUS. Please refer to the Instructions for Use of ALLOY PRIMER.

A-5. 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.

- 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.
- If the product adheres to clothing, wash it off with water.
- After each use, remove the needle tip from the syringe and recap the syringe immediately and tightly.
- Etching the vital dentin may cause post-operative sensitivity.

[Dental light-curing unit]

- Use it according to the Instructions for Use for the dental light-curing unit.
- Do not look directly at the light source. Protective glasses are recommended.
- 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 evaluating device at appropriate intervals.
- 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 has to be light-cured, it is advisable to divide the area into several sections and light-cure each section separately.
- 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.

3. Storage precautions

- The product must be used by the expiration date indicated on the package.
- The Paste, Tooth Primer and CLEARFIL CERAMIC PRIMER PLUS must be stored (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.
- The product must be kept away from extreme heat, direct sunlight or a flame.
- 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.
- 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.

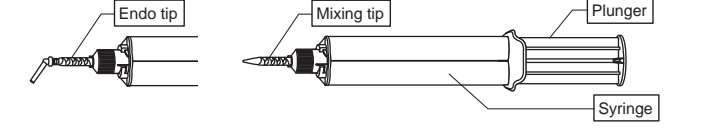
<Principal ingredients>

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| <ol style="list-style-type: none"> Paste: Universal (A2), Clear, Brown (A4), White, Opaque <ul style="list-style-type: none"> • Bisphenol A diglycidylmethacrylate (Bis-GMA) • Triethylene glycol dimethacrylate (TEGDMA) • Hydrophobic aromatic dimethacrylate • Hydrophilic aliphatic dimethacrylate • Initiators • Accelerators • Silanated barium glass filler • Silanated fluoroaluminosilicate glass filler • Colloidal silica The Paste, Tooth Primer and CLEARFIL CERAMIC PRIMER PLUS must be stored (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. <ul style="list-style-type: none"> • Silanated barium glass filler • Silanated fluoroaluminosilicate glass filler • Colloidal silica | <ol style="list-style-type: none"> Paste: Universal (A2), Clear, Brown (A4), White, Opaque <ul style="list-style-type: none"> • Bisphenol A diglycidylmethacrylate (Bis-GMA) • Triethylene glycol dimethacrylate (TEGDMA) • Hydrophobic aromatic dimethacrylate • Hydrophilic aliphatic dimethacrylate • Accelerators • Silanated barium glass filler • Silanated fluoroaluminosilicate glass filler • Colloidal silica The Paste, Tooth Primer and CLEARFIL CERAMIC PRIMER PLUS must be stored (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. <ul style="list-style-type: none"> • Bisphenol A diglycidylmethacrylate (Bis-GMA) • Hydrophobic aromatic dimethacrylate • Hydrophilic aliphatic dimethacrylate • Accelerators • Silanated barium glass filler • Silanated aluminum oxide filler • Accelerators • Pigments |
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The total amount of inorganic filler is approximately 38 vol%.

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

Device components:



- | | |
|---|--|
| <ol style="list-style-type: none"> Try-In Paste: Universal (A2), Clear, Brown (A4), White, Opaque <ul style="list-style-type: none"> • Glycerol • Silanated colloidal silica • Colloidal silica • Pigments Tooth Primer <ul style="list-style-type: none"> • 10-Methacryloyloxydecyl dihydrogen phosphate (MDP) • 2-Hydroxyethyl methacrylate (HEMA) • Hydrophilic aliphatic dimethacrylate • Accelerators K-ETCHANT Syringe <ul style="list-style-type: none"> • Phosphoric acid • Water | <ol style="list-style-type: none"> CLEARFIL CERAMIC PRIMER PLUS <ul style="list-style-type: none"> • 3-Methacryloyloxypropyl trimethoxysilane • 10-Methacryloyloxydecyl dihydrogen phosphate (MDP) • Ethanol Accessories <ul style="list-style-type: none"> • Mixing tip • Endo tip (E) • Needle tip (E) (for K-ETCHANT Syringe) • Applicator brush (fine «silvers») • Mixing dish |
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VIII. CLINICAL PROCEDURES

A. Standard procedure [Indications 1], [2] and [3]]

- Cementation of crowns, bridges, inlays and onlays
- Cementation of veneers
- 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.

A-2. Trial fitting and adjusting a restoration

- (1) Trial fit the prosthetic restoration to check its fit on the prepared tooth, as necessary.
- (2) If necessary, apply the selected shade of Try-in Paste onto the cementation surface of the restoration and trial fit the restoration onto the prepared tooth. Remove excess Try-in Paste from the margins with a brush. The shades of Try-in Paste correspond to those of the hardened cement (PANAVIA V5 Paste).
- (3) Check the shade for best color matching, and then remove the restoration. Using water, completely wash the Try-in Paste from the inner surface of the restoration and the prepared tooth surface.

A-3. Conditioning 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. KATANIA 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 kgf/cm²; 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 restoration, 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 restoration material, or apply K-ETCHANT Syringe over the adherent surface and leave for 5 seconds.
 - (2) Clean the adherent surface with water and dry.

B-5. Removing the excess cement and final curing

- B-5-a. For Universal (A2), Clear, Brown (A4) or White shades:*
- (1) Remove any excess cement. See section "A-8-a" (1).
 - (2) Finally, cure the cement using either of the following two methods:
 - Blasting the adherent surface by blasting with alumina powder (30-50μm) using air pressure of 0.1-0.2 MPa (1-2 kgf/cm²; 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.
 - Clean the prosthetic restoration in an ultrasonic cleaning unit for 2 minutes followed by drying it with an air stream.

Prosthetic restorations that are not translucent (e.g. metal crowns):
Allow the cement to chemical-cure by letting it set after placement of the prosthetic restoration. See the below table.

Table3: Setting time (for cementation of prosthetic restorations on implant abutments and frames)	
Final-curing after placement of the restoration	
self-cure (37°C/ 99°F)	5 min.
self-cure (23°C/ 73°F)	10 min.

Prosthetic restorations that are translucent (e.g. ceramic inlays):
Light-cure the entire surface of the prosthetic restoration using the dental curing unit. If the area you want to light-cure is larger than the light emitting tip, divide the exposure process into a few applications.

Please confirm the curing time by referencing Table 1.

B-5-b. For Opaque shade:

- (1) Treat the excess cement. See section "A-8-b" (1).
- (2) Allow the cement to chemical-cure by letting it set after placement of the prosthetic restoration. See the Table 3.

C. Standard procedure [Indications [5]]

[5] Cementation of posts and cores

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

- (1) Prepare the endodontically fitted root canal 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 thickness into 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.

C-2. Blasting the core or post

Blast the core or post surface according to step "A-3". Do not blast glass fiber posts due to potential damage.

C-3. Treatment of the core or post

For a metal core and metal post:
Apply CLEARFIL CERAMIC PRIMER PLUS to the surface of the core or post with an applicator brush. After application, dry the entire adherent surface sufficiently using mild, oil-free air flow.

[NOTE]

For optimal performance, ALLOY PRIMER can be used on the surface of the precious metal alloy instead of CLEARFIL CERAMIC PRIMER PLUS. Please refer to the Instructions for Use of ALLOY PRIMER.

For a resin core, glass-fiber post and ceramic post:

- (1) Apply K-ETCHANT Syringe to the core or post surface. Leave the gel in place for 5 seconds before washing and drying.
- (2) Apply CLEARFIL CERAMIC PRIMER PLUS to the surface of the core or post with an applicator brush. After application, dry the entire adherent surface sufficiently using mild, oil-free air flow.

C-4. Application of Tooth Primer

- (1) Apply the Tooth Primer to the root canal and the cavity wall with an applicator brush and leave it in place for 20 seconds. Use caution not to allow saliva or exudates to contact the treated surfaces.
- (2) Use a paper point to carefully remove any excess Tooth Primer liquid from the root canal or cavity, especially from the corners of the cavity and inside the root canal.
- (3) Thoroughly dry the entire adherent surface sufficiently by blowing mild, oil-free air. Use a vacuum aspirator to prevent the Tooth Primer liquid from dispersing.

C-5. Preparing the syringe and accessories

See section "A-6".

C-6. Placing the core or post

- (1) Apply the mixed paste over the entire adherent surface of the core or post, or the entire tooth surface within the cavity. If the paste is applied directly into the cavity, you must begin step (2) within 60 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 canal.

C-7. Treatment of the excess cement

For cores:
See section "A-8-a" (1)* or "A-8-b" (1)*.

For dental posts:
Using an applicator brush, spread the excess cement over the coronal base and post head.

C-8. Curing

Light-cure the margins of the core or post. See Table 1 in "A-8". For the opaque shade, allow the cement to chemical-cure by letting it set for 3 minutes after placement of the core or post.

C-9. Preparing for the final restoration

Seat the core in place for approximately 6 minutes and make sure the cement has been completely cured before preparing the abutment tooth.

For dental posts:

After placing the dental post, place the core buildup composite resin according to the Instructions for Use.

Prepare the abutment tooth 6 minutes after seating the dental post.

D. Standard procedure IV [Indications [6]]

[6] Amalgam bonding

D-1. Cleaning of the tooth structure

Clean the cavity and provide moisture control in the usual manner.

D-2. Application of Tooth Primer, Preparing the syringe and accessories

See section "A-5" and "A-6".

D-3. Placing the amalgam

- (1) Apply the mixed paste over the entire tooth surface within the cavity. You must begin step (2) within 60 seconds after application of the cement.
- (2) The triturated amalgam should be condensed on the unset mixed paste. Occlusal carving can be accomplished in the usual manner.

D-4. Removing the excess cement and final curing

See section "A-8".

[CAUTION]

Federal (U.S.A.) law restricts this device to sale by or on the order of dental professionals. [WARNING]

Kuraray Noritake Dental Inc. will replace any product that is proved to be defective. Kuraray Noritake Dental 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]

*PANAVIA™ and CLEARFIL™ are trademarks of KURARAY CO., LTD. *KATANIA is a trademark of NORITAKE CO., LIMITED.

B. Standard procedure [Indications [4]]

[4] Cementation of prosthetic restorations on implant abutments and frames

- Cleaning the implant abutment or frame, Trial fitting and adjusting a restoration, Conditioning the prosthetic restorative surface
See section "A-1", "A-2" and "A-3".

B-2. Application of CLEARFIL CERAMIC PRIMER PLUS

Apply CLEARFIL CERAMIC PRIMER PLUS to the internal surface of the restoration and adherent surface of implant abutments or frames with an applicator brush. After application, dry the entire adherent surface sufficiently using mild, oil-free air flow.

[NOTE]

For optimal performance, ALLOY PRIMER can be used on the surface of the precious metal alloy instead of CLEARFIL CERAMIC PRIMER PLUS. Please refer to the Instructions for Use of ALLOY PRIMER.

B-3. Preparing the syringe and accessories

See section "A-6".

B-4. Cementing the prosthetic restoration

- (1) Apply the mixed paste onto the entire adherent surface of the prosthetic restoration.
- (2) Place the prosthetic restoration on the implant abutment or frame.

B-5. Removing the excess cement and final curing

B-5-a. For Universal (A2), Clear, Brown (A4) or White shades:

- (1) Remove any excess cement. See section "A-8-a" (1).
- (2) Finally, cure the cement using either of the following two methods:

FRANÇAIS MODE D'EMPLOI

I. INTRODUCTION

PANAVIA V5 est un système de ciment résine adhésif. PANAVIA V5 est composé d'une pâte de ciment, d'un Endo tip, d'une tige, d'un poussoir, d'un Primer, de CLEARFIL CERAMIC PRIMER PLUS et d'un K-ETCHANT Syringe. La pâte est un ciment résine radio-opaque à double polymérisation (photo et/ou auto-polymérisation), libérant du fluorure pour les céramiques (disilicate de lithium, zirconie, etc), les céramiques hybrides, les résines composites, et les restaurations métalliques. Il est fourni dans un système de livraison Automix qui peut mesurer des quantités égales de deux composants. Il est disponible dans les 5 teintes suivantes: Universal (A2), Clear, Brown (A4), White et Opaque. La teinte Opaque doit être auto-polymérisée pour obtenir la polymérisation finale en raison de sa forte opacité. Le Try-in Paste est un matériau d'adaptation à la teinte qui a quasiment la même couleur et la même transparence que le mélange durci de la Pâte. Le Tooth Primer est un apprêt auto-mordant pour les structures des dents qui accélère la polymérisation de la pâte. CLEARFIL CERAMIC PRIMER PLUS est un apprêt prosthétique universel dentaire qui fournit une surface adhésive renforcée aux

