



SELF-ADHESIVE RESIN CEMENT

PANAVIA™ SA Cement Universal

ENGLISH INSTRUCTIONS FOR USE

I. INTRODUCTION

PANAVIA SA Cement Universal is a dual-cure (light- and/or self-cure), fluoride releasing, radiopaque self-adhesive resin cement for ceramic (porcelain, lithium disilicate, zirconia, etc.), composite resin, and metal restorations. It has a choice of Automix delivery (equal amounts of two components are combined through a mixing tip) or Handmix (equal amount of two components are combined on a mixing pad).

II. INDICATIONS

PANAVIA SA Cement Universal is indicated for the following uses:

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

III. CONTRAINDICATIONS

Patients with a history of hypersensitivity to methacrylate monomers

IV. POSSIBLE SIDE EFFECTS

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.

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. This 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 using the product, cover the patient's eyes with a towel 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 the patient from accidentally swallowing the product.
7. Avoid looking directly at the dental curing light when curing the product.
8. This product contains a trace amount of surface treated sodium fluoride (less than 1%). Using on children under the age of 6 may have a potential risk of fluorosis.
9. Dispose of this product as a medical waste to prevent infection.

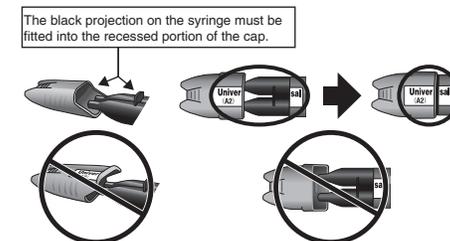
<Automix>

1. Do not reuse the mixing tip and the endo tip to prevent cross-contamination. The mixing tip and the endo tip are single use only. Discard them after use.
2. 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.

2. Handling and manipulation precautions

1. The product must not be used for any purposes other than specified in [III.INDICATIONS].
2. The use of this product is restricted to licensed dental professionals.
3. Do not use the product as a provisional cement. This material is designed to use for permanent cementation.
4. Use a rubber dam to prevent contamination and to control moisture.
5. Use a pulp capping agent (e.g. calcium hydroxide material) 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 adherend surface. Failure to do so might weaken the bond strength to the tooth structure.
7. Clean the cavity sufficiently to prevent poor bonding. If the adherend surface is contaminated with saliva or blood, wash it thoroughly and dry before cementation.

8. Do not mix the product with any other dental materials.
9. Completely remove any lining materials, amalgam and temporary sealing materials when preparing the cavity to avoid poor adhesion.
10. To prevent poor performance or poor handling characteristics, observe the specified light-curing times and other handling requirements.
11. If the instruments of this product are damaged, protect yourself from any danger and immediately discontinue their use.
12. 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.
13. When inserting the paste directly into the cavity or root canal, placement of the prosthetic restoration should be done within 40 seconds (within 30 seconds when using CLEARFIL Universal Bond Quick). Failure to do so will cause premature polymerization of the paste, due to the effects of temperature and/or water in the oral cavity.
14. 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.
15. Be careful to prevent unnecessary exposure to direct sunlight or surgery operating lights, otherwise the paste inside the tip may harden, leading to a shortened working time.
16. Make sure to dispense an equal amount of Paste A & B for mixing.
17. Excess cement can be removed after light-curing for 2-5 seconds when using the tack-cure method. When the cement is used in combination with CLEARFIL Universal Bond Quick, the setting time of the excess cement will be faster (1 to 2 seconds). The cement can also be allowed to self-cure for 2-4 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 cement, it should be used in the direction that does not lift the prosthetic restoration.
18. 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, and make sure to prevent the excess cement from entering another root canal.
19. Do not immerse the syringe into a disinfecting solution.
20. If the paste at the tip of the syringe has hardened after a long interval, squeeze out small amounts of both pastes.
21. Replace the syringe cap in the proper direction as soon as possible after use. If excess paste gets deposited at the tip of syringe, wipe it using a piece of gauze or cotton before replacing the cap. If the direction of the replaced cap is incorrect, Paste A might come into contact with Paste B at the tip of the syringe. When the heterogeneous pastes contact each other, the contacted portion of the pastes will cure.
 - <Automix>
 1. In multiple prosthetic restorations, complete the application of the cement to all the restorations within 1 minute of initial dispensing. If application takes more than 1 minute, replace the first mixing tip or endo tip with a new one.
 - <Handmix>
 1. Be sure there is no condensation on the mixing pad or spatula before using them; the presence of water can shorten the working time of the mixed paste.



- If the direction of the replaced cap is incorrect, Paste A might come into contact with Paste B at the tip of the syringe. When the heterogeneous pastes contact each other, the contacted portion of the pastes will cure.
2. When inserting the paste directly into the cavity or root canal using a composite delivery syringe, placement of the prosthetic restoration should be completed within 40 seconds (within 30 seconds when using CLEARFIL Universal Bond Quick).

[Dental light-curing unit]

1. Do not look directly at the light source. Protective glasses are recommended.
2. 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 cement surface as possible. If a large cement surface is 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 product must be stored at 2-25°C/ 36-77°F when not in use. When the product container is stored in the refrigerator, it should stay at room temperature for 15 minutes before use in order to restore its normal viscosity and curing properties.
- The product must be kept away from extreme heat or direct sunlight.
- The product must be stored in a proper place where only dental practitioners can access.

VII. COMPONENTS

1. Shade

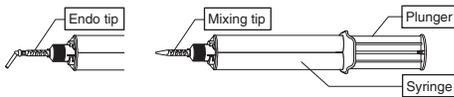
PANAVIA SA Cement Universal is available in the following 3 shades; Universal (A2), Translucent or White.

2. Components

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

- Paste A and B: Universal (A2), Translucent or White
- Accessories
 - <Automix>
 - Mixing tip
 - Endo tip

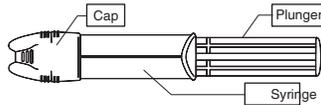
Device components.



<Handmix>

- Mixing pad
- Mixing spatula

Device components.



3. Ingredients

Principal ingredients

(1) Paste A

- 10-Methacryloyloxydecyl dihydrogen phosphate (MDP)
- Bisphenol A diglycidylmethacrylate (Bis-GMA)
- Triethyleneglycol dimethacrylate (TEGDMA)
- Hydrophobic aromatic dimethacrylate
- 2-Hydroxymethacrylate (HEMA)
- Silanated barium glass filler
- Silanated colloidal silica
- dl-Camphorquinone
- Peroxide
- Catalysts
- Pigments

(2) Paste B

- Hydrophobic aromatic dimethacrylate
- Silane coupling agent
- Silanated barium glass filler
- Aluminum oxide filler
- Surface treated sodium fluoride (Less than 1%)
- dl-Camphorquinone
- Accelerators
- Pigments

<Automix>

The total amount of inorganic filler is approx. 40 vol%. The particle size of inorganic fillers ranges from 0.02 µm to 20 µm.

<Handmix>

The total amount of inorganic filler is approx. 43 vol%. The particle size of inorganic fillers ranges from 0.02 µm to 20 µm.

VIII. CLINICAL PROCEDURES

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

- Cementation of crowns, bridges, inlays and onlays
- Cementation of prosthetic restorations on implant abutments and frames
- Cementation of adhesion bridges and splints

A-1. Conditioning the prepared tooth (including metal or composite); prosthetic frame and implant abutment surfaces

- When cementing in the oral cavity, remove the temporary sealing material and temporary cement in the usual manner, and clean the cavity using moisture control.
- Trial fit the prosthetic restoration to check its fit on the prepared tooth (including metal or composite); frame or implant abutment.

Treatment of enamel

When cementing to uncut enamel or using with adhesion bridges, apply phosphoric acid (e.g. K-ETCHANT Syringe) to the enamel surface and leave for 10 seconds, then rinse and dry the surface.

A-2. Conditioning the prosthetic restoration surface

Please follow the Instructions for Use of the restoration material. In the absence of specific instructions, we recommend the following procedure:

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

Roughen the adherent surface by blasting with 30 to 50 µm alumina powder at an air pressure of 0.1-0.4 MPa (14-58 PSI/ 1-4 bar). The air pressure should be properly adjusted to suit the material and/ or shape of the prosthetic restoration, using caution to prevent chipping. After blasting, clean the prosthetic restoration by using an ultrasonic cleaning unit for 2 minutes followed by drying it with an air stream.

If the adherent surface is silica-based ceramic (lithium disilicate, etc.)

Roughen the adherent surface by blasting with 30 to 50 µm alumina powder at an air pressure of 0.1-0.2 MPa (14-29 PSI/ 1-2 bar), or apply hydrofluoric acid solution in accordance with the Instructions for Use of the restoration material, and thoroughly wash and dry the surface.

A-3. Preparing the syringe; accessories and paste

<Automix>

- Attach a mixing tip or an endo tip to the syringe in the usual manner.

[CAUTION]

Before attaching a mixing tip or an endo tip, extrude small amounts of the two pastes, making sure equal amounts are being dispensed through the two outlets of the syringe, and discard them. If equal amounts of paste are not used, there is a possibility of poor polymerization.

[NOTE]

- After use, the syringe should be stored with the cap. When 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 mixed paste out of the syringe, remove hardened paste by using an appropriate instrument.
- When changing the direction of the endo tip, rotate the distal attachment and use caution not to bend the slender dispensing portion of the tip.

<Handmix>

- Make sure to dispense an equal amount of the Paste A&B on the mixing pad.
- Mix Paste A&B for 10 seconds at room temperature (23°C/ 73°F). The mixed paste must be covered with a light-blocking plate and should be used within 2 minutes after mixing. High temperatures and strong light can shorten the working time of the mixed paste.

[NOTE]

- After use, the syringe should be stored with the cap. When you put the cap back on the syringe before storage, make sure the cap is free of paste.

A-4. Cementing the prosthetic restoration

- Apply the mixed paste over the entire adherent surface of the prosthetic restoration or the entire tooth surface within the cavity. If the paste is applied directly on the entire prepared tooth intra-orally, you must begin step (2) within 40 seconds after application of the paste.
- Place the prosthetic restoration on the prepared tooth (including metal or composite); prosthetic frame or implant abutment.

[NOTE]

CLEARFIL Universal Bond Quick can be used on the tooth structure to increase adhesion, if preferred. Please refer to the Instructions for Use of CLEARFIL Universal Bond Quick.

[CAUTION <Automix>]

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 barrier (e.g. a poly bag) to prevent saliva and blood contamination. Disinfect the syringe by wiping it with an absorbent cotton with alcohol both before and after use.

A-5. Removing the excess cement

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

Light-curing (Tack-cure)

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

[CAUTION]

When removing the excess cement after tack-curing, 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 cement, it should be used in the direction that does not lift the prosthetic restoration.

[NOTE]

When the cement is used in combination with CLEARFIL Universal Bond Quick, the setting time of the excess cement will be faster (1 to 2 seconds).

Chemical-curing

Leave any excess cement for 2 to 4 minutes after placement of the prosthetic restoration. Remove the tack-cured excess cement using a dental explorer.

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 set 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 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 the following table:

Table: Curing time for type of light source.

Type of light source (Light intensity)	Curing time
High-intensity BLUE LED * (More than 1500 mW/cm ²)	Twice for 3 to 5 sec.
BLUE LED * (800-1400 mW/cm ²)	10 sec.
Halogen lamp (More than 400 mW/cm ²)	10 sec.

The effective wavelength range of each dental curing unit must be 400 - 515 nm.

* Peak of emission spectrum: 450 - 480 nm

The working times and setting times depend on the ambient and oral temperature as indicated below. When oral temperature is not specified in this Instruction for Use, it understood to be 37°C/ 99°F. Note that this cement is a dual-curing cement and therefore sensitive to artificial and natural light.

Table: Working time and setting time (for cementation of crowns, bridges, inlays, onlays and adhesion bridges)

Working time after initial dispensing (23°C/ 73°F)	Automix: 1 min.
	Handmix: 2 min.
Working time after insertion of the paste into the cavity (37°C/ 99°F) (when used with CLEARFIL Universal Bond Quick)	40 sec.
	(30 sec.)
Tack-curing for removal of excess cement	
light-cure	2 - 5 sec.
(when used with CLEARFIL Universal Bond Quick)	(1 - 2 sec.)
self-cure (37°C/ 99°F)	2 - 4 min.
self-cure (23°C/ 73°F)	5 - 7 min.
Final-curing after placement of the restoration	
light-cure (LED)	10 sec. *
self-cure (37°C/ 99°F)	5 min.
self-cure (23°C/ 73°F)	12 min.

* Curing time by using BLUE LED (light intensity: 800-1400 mW/cm²)

A-7. Shaping and polishing

Shape any remaining uneven areas on the edges of the restoration and polish the marginal areas using diamond devices, alumina oxide coated discs, and/or diamond polishing paste. Then, check the occlusion.

B. Standard procedure II (Indications [4])

[4] Cementation of post and cores

B-1. Preparing a cavity and trial fit of 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 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.

B-2. Blasting the core or post

Blast the core or post surface according to step "A-2. Conditioning the prosthetic restoration surface". Do not blast glass fiber posts due to potential damage.

B-3. Preparing the syringe; accessories and paste

See section "A-3."

B-4. Placing the core or post

- (1) Apply the mixed paste over the entire adherent surface of the core or post, or the entire surface within the cavity. If the mixed paste is applied directly into the cavity, you must complete 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.

[NOTE]

CLEARFIL Universal Bond Quick can be used on the tooth structure to increase adhesion, if preferred. In this case, if the mixed paste is applied directly into the cavity, you must complete step (2) within 30 seconds after application of the cement. Please refer to the Instructions for Use of CLEARFIL Universal Bond Quick.

B-5. Spreading the excess cement

Using a disposable brush tip, spread the excess paste over the coronal base and post head.

B-6. Light-curing

Light-cure the margins of the core or post. See table "Curing time for type of light source" in A-6.

B-7. Preparing for the final restoration

For cores

Seat the core in place for approximately 10 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 10 minutes after placing the dental post.

C. Standard procedure III (Indications [5])

[5] Amalgam bonding

C-1. Cleaning of tooth structure

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

C-2. Preparing the syringe; accessories and paste

See section "A-3."

C-3. Placing the amalgam

- (1) Apply the mixed paste over the entire tooth surface within the cavity. You must begin step (2) within 40 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.

[CAUTION <Automix>]

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 barrier (e.g. a poly bag) to prevent saliva and blood contamination. Disinfect the syringe by wiping it with an absorbent cotton with alcohol both before and after use.

C-4. Removing the excess cement

Any excess paste remaining at the margins can be removed by light-curing or chemical-curing (refer to section "A-5").

C-5. Final curing

Allow the cement to chemical-cure by letting it set for 5 minutes after placement of the Amalgam or light-cure the margins of Amalgam using the instruction for the dental curing unit (refer to section "A-6"). If the area you want to light-cure is larger than the light emitting tip, divide the exposure process into a few applications.

[CAUTION]

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

[WARRANTY]

Kuraray Noritake Dental Inc. will replace any product that is proven 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]

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