

Adhesive Resin Cement

ESTECEM IICE
REF BIS02**ENGLISH**

Read all information, precautions and notes before using.

PRODUCT DESCRIPTION AND GENERAL INFORMATION

ESTECEM II is a dual-cure (light and/or self-cure), radiopaque, adhesive resin cement system with excellent handling, esthetic and adhesive properties to teeth and all prosthetic materials. The main components of the ESTECEM II KIT are the PASTE (A/B) and TOKUYAMA UNIVERSAL BOND. The PASTE is supplied in an automix syringe and is available in various sizes (1.0ml, 3.0ml, Clear, Brown and White). TOKUYAMA UNIVERSAL BOND promotes the adhesion of PASTE to tooth structure. TOKUYAMA UNIVERSAL BOND also enhances the adhesion of PASTE to all prosthetic materials.

2. The PASTE contains Bisphenol A diglycidylmethacrylate (Bis-GMA), Triethylene glycol dimethacrylate (TEGDMA), Bisphenol A polyethoxy methacrylate (Bis-MEEP), and Silica-Zinc Filler (Load 74 wt%).

3. The TOKUYAMA UNIVERSAL BOND contains Bisphenol A diglycidylmethacrylate (Bis-GMA), Triethylene glycol dimethacrylate (TEGDMA), Bisphenol A-polyethoxy-methacrylate (Bis-MEEP), Peroxide, Camphorphenol, Acetone, Isopropanol and Purified water.

4. **Dissolve of TOKUYAMA UNIVERSAL BOND**

Allow TOKUYAMA UNIVERSAL BOND to reach room temperature prior to use. Open the bottle by removing the cap and dispense one drop each of TOKUYAMA UNIVERSAL BOND A and B into the mixing well or disposable mixing well. Mix thoroughly with a disposable applicator.

- Complete the application within 1 minute of dispensing when using the mixing well since TOKUYAMA UNIVERSAL BOND contains volatile solvents. After mixing, the color of TOKUYAMA UNIVERSAL BOND changes gradually based on the reaction of the catalyst of TOKUYAMA UNIVERSAL BOND, this is normal and does not indicate a problem with TOKUYAMA UNIVERSAL BOND.

5. **Restorative Preparation with the TOKUYAMA UNIVERSAL BOND**

1) Apply the disposable applicator, apply the mixed TOKUYAMA UNIVERSAL BOND on the surface to be bonded.

- Ensure TOKUYAMA UNIVERSAL BOND covers all surfaces where the PASTE will be applied.

- DO NOT over apply. One application of TOKUYAMA UNIVERSAL BOND is sufficient.

- DO NOT allow saliva, blood, oil, water etc. to come in contact with the surface to be bonded. If the treated surface is contaminated, thoroughly rinse with water, dry and re-apply fresh TOKUYAMA UNIVERSAL BOND.

- DO NOT wait too long after the application of TOKUYAMA UNIVERSAL BOND. Air dry with 30 seconds after application to ensure the appropriate film thickness.

2) **After-drying**

Use an oil-free air/water syringe, apply mild air to the surface. Use a vacuum aspirator to prevent spatter of the TOKUYAMA UNIVERSAL BOND.

- Be sure to dry the surface after TOKUYAMA UNIVERSAL BOND is applied.

6. **Tooth (adherent surface) Pretreatment with the TOKUYAMA UNIVERSAL BOND**

1) Apply the disposable applicator, apply the mixed TOKUYAMA UNIVERSAL BOND on the surface to be bonded.

- Ensure TOKUYAMA UNIVERSAL BOND covers all surfaces where the PASTE will be applied.

- DO NOT over apply. One application of TOKUYAMA UNIVERSAL BOND is sufficient.

- DO NOT allow saliva, blood, oil, water etc. to come in contact with the surface to be bonded. If the treated surface is contaminated, thoroughly rinse with water, dry and re-apply fresh TOKUYAMA UNIVERSAL BOND.

- DO NOT wait too long after the application of TOKUYAMA UNIVERSAL BOND. Air dry with 30 seconds after application to ensure the appropriate film thickness.

7) **Avoid contact of the PASTE, or TOKUYAMA UNIVERSAL BOND with eyes, mucosal membrane, skin and clothing.**

- If the PASTE or TOKUYAMA UNIVERSAL BOND comes in contact with the eyes, thoroughly rinse with water and immediately contact an ophthalmologist.

- If the PASTE or TOKUYAMA UNIVERSAL BOND comes in contact with the mucosal membrane, wipe the affected area immediately, and thoroughly flush with water after the restoration is seated. TOKUYAMA UNIVERSAL BOND affected areas may whiten from poor coagulation, but such whitening should disappear within 24 hours. If such whitening does not disappear within 24 hours, immediately contact a physician, and the patient should be advised.

- If the PASTE or TOKUYAMA UNIVERSAL BOND comes into contact with the skin or clothing, immediately saturate the area with alcohol-soaked cotton swab or gauze.

- Instruct the patient to rinse his mouth immediately after treatment.

8) **Storage**

- Do not ingest or aspirate. BOND should not be ingested or aspirated.

- Ingestion or aspiration may cause serious injury.

9) To avoid the unintentional ingestion of the PASTE or TOKUYAMA UNIVERSAL BOND, do not leave it unsupervised within the reach of patients and children.

10) DO NOT expose TOKUYAMA UNIVERSAL BOND or the vapor to open flame because it may catch fire.

11) DO NOT use on electronic devices or other manufacturers.

12) To avoid cross infection or lowering bond strength, DO NOT reuse the disposable applicator and the disposable mixing well. Clean the mixing well thoroughly with alcohol after each use.

13) DO NOT ESTECEM II directly to the cavity being in close proximity to the pulp. Pulp protection with glass ionomer lining or calcium hydroxide is recommended. DO NOT use EUGENOL BASED MATERIALS to protect the pulp as these materials will inhibit the curing of TOKUYAMA UNIVERSAL BOND.

14) When using a light-curing unit, protective eye shields, glasses or goggles should be worn at all times.

15) Be aware that when a restoration is chipped from misaligned occlusion or bruxism (clenching, grinding or tapping), the repaired restoration may chip again.

16) DO NOT mix PASTE or TOKUYAMA UNIVERSAL BOND with other brands of paste, primers or bonding agents.

17) The PASTE or TOKUYAMA UNIVERSAL BOND should be brought to room temperature before using. After removing from the refrigerator, allow the product to sit for 20 minutes or until it reaches room temperature.

PRECAUTIONS FOR PASTE

1) Use the Cement Mixing Tip or Mini Mixing Tip S included in this KIT when extruding the mixed PASTE.

2) Use an clean instrument or explorer for the application or removal of the PASTE.

3) To avoid unexpected hardening of the PASTE, after use move the nozzle tip from the automix syringe. Use a clean clear or rinsable tip with the excess pastes on the tip of syringe prior to recapping the syringe and the cap should be sealed with the syringe at the time of purchase.

PRECAUTIONS FOR TOKUYAMA UNIVERSAL BOND

1) To avoid damage to the tooth structure, TOKUYAMA UNIVERSAL BOND should not be opened immediately after taking out of the refrigerator.

2) Use the mixing well or disposable mixing well provided when dispensing and mixing of TOKUYAMA UNIVERSAL BOND. If TOKUYAMA UNIVERSAL BOND is not dispersed into the rubber mixing it may be difficult to remove cured TOKUYAMA UNIVERSAL BOND from mixing well.

3) Some materials and modisms (hemostatic material) inhibit setting/adhesion of TOKUYAMA UNIVERSAL BOND.

DO NOT use products that contain:

- amines, chloride,

- ferric sulfate,

- calcium sulfate,

- aluminum sulfate,

- diamine silver fluoride [molecular formula: Ag(NH₃)₂F]

4) TOKUYAMA UNIVERSAL BOND does not adhere to tooth structure immediately after application of materials that contain:

- hydrogen peroxide (oxydol),

- sodium hypochlorite.

We advise avoiding the use of these materials on the day of cementation, however these materials can be used for root canal treatment as the inhibition caused by these materials usually evaporates within five days.

5) Adhesive bond of bottles of TOKUYAMA UNIVERSAL BOND A and B vertically when dispensing. Do not hold the bottle diagonally or horizontally while dispensing; this could cause the primer to flow back into the nozzle and become contaminated.

STORAGE

1) Store under refrigeration at temperatures between 0 to 10 °C (32 to 50°F).

2) Keep away from heat, direct sunlight, sparks and open flames.

3) DO NOT use after the indicated expiration date on the syringe/bottle/package.

DISPENSAL

- To dispose of the PASTE, extrude unused paste from the automix syringe, mix and allow paste to harden before disposal.

- Unused TOKUYAMA UNIVERSAL BOND is to be absorbed into an inert absorbent material such as gauge or cotton, and disposed of in accordance with local regulations.

CLINICAL PROCEDURES

1. **Tooth Preparation**

Remove contamination from the tooth surface such as plaque, temporary cement residue, oil from materials to test down fit, oil must from a hand-piece, saliva, blood and exudates fluids by rinsing with water, thorough scaling or cleaning the surface of the tooth with alcohol.

Thoroughly rinse and dry the surface.

- If the adherent surface involves uncut enamel, apply etching agent to the uncut enamel. See section "Selective-enamel-etch technique".

- DO NOT desicate the vital tooth. Desication can lead to post-operative sensitivity.

2. **Etching of the tooth structure (optional)**

Clinical results can be achieved by the application of the adhesive. Selectively etching the enamel or using the "total etching procedure" can achieve higher adhesive values.

(a) Selective-enamel-etch technique

Apply phosphoric acid gel only to the enamel surrounding the margin of prepared cavity and leave phosphoric acid gel in place for 10-15 seconds. Rinse the etched surface thoroughly (at least 15 seconds) with water, and then dry with mild air.

3. **Restorative Preparation**

Follow the procedure below depending on the material to be restored.

- Use either the Porcelain and Composite materials.

Roughen the interior of the restoration by sandblasting (0.1 to 0.2MPa), air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.

4. **Porcelain**

DO NOT roughen the surface. Prepare the interior of the restoration, providing a clean and fresh surface for adhesion. Thoroughly rinse and dry the surface.

5. **Metal Restorations**

Roughen the area by sandblasting (0.3 to 0.5MPa), air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.

6. **CLINICAL PROCEDURES**

7. **Initial Preparation**

Remove contamination from the tooth surface such as plaque, temporary cement residue, oil from materials to test down fit, oil must from a hand-piece, saliva, blood and exudates fluids by rinsing with water, thorough scaling or cleaning the surface of the tooth with alcohol.

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19. **CLINICAL PROCEDURES**

20. **Initial Preparation**