

Controlled Medical Device-Dental Etching Material

Zero Flow Etchant

[Product description]

[Intended purpose]

This product is used for etching of dental enamel and dental restorations (excepting dental technician’s procedures).

[Indications]

Etching of dental enamel and dental restorations (excepting dental technician’s procedures).

[Intended users]

Dentist (Educated dental professionals who have theoretical and practical knowledge on usage of dental products.)

Patient target group: all patients requiring dental treatment, unless the patient’s condition like a known allergy limits the use.

[Clinical Benefit]

Enhancing the adhesion of dental bonding material by cleaning and/or surface-roughening of dental enamel and restorations.

[Contradictions and Prohibitions]

- DO NOT USE THIS PRODUCT ON PATIENTS WITH A KNOWN HISTORY ALLERGY SUCH AS IRRITATION.
- DO NOT REUSE NEEDLE TIPS.

[Shape, Composition and Principle]

This product contains the ingredients listed below:

State	Ingredients
Paste	Phosphoric acid, purified water, thickening agents, dye.

Principle: Using the acidity of phosphoric acid, this product achieves cleaning and surface-roughening of natural teeth and dental restorations.

Accessories: Disposable Pre-Bent Needle Tips

- 21 ga - 5 pcs (inner diameter: 0.6 mm, green)
- 25 ga - 5 pcs (inner diameter: 0.3 mm, blue)

[Instructions for Use]

1) Preparation

- (1) Turn the safety plug (the cap) counter-clockwise and remove it from the syringe.
- (2) Turn the appropriate needle tip clockwise on the end of the syringe to attach.

2) Etching of the tooth substance

- (1) If the surface of enamel to be etched is untreated, clean the surface as usual. Rinse it thoroughly with water at the moment.
- (2) Confirm that the part to be etched is thoroughly cleaned and dried. Exclusion of moisture with a rubber dam is recommended.
- (3) Apply this product to the enamel and leave it for 15 sec or more.
 - When used as a pretreatment for orthodontic applications (brackets, anchors, etc.), leave it on for at least 30 seconds.
- (4) Rinse thoroughly with water while vacuuming until the color of this product has disappeared. Then dry with oil-free air.
 - Rinse with water for 10 sec or more. Rinse additionally with water if a large amount is applied.
- (5) Confirm that the etched tooth surface is cloudy. If it is not cloudy, repeat steps (2)-(4).

3) Cleaning of restoration surface (products containing inorganic fillers such as ceramics, direct composite resin, indirect composite resin etc.)

- (1) Thoroughly rinse and dry the adherend surface.
- (2) Squeeze this product onto the adherend surface and rub lightly with a micro-brush for 20 sec. or more while applying.
- (3) Leave it for 15 sec or more.
- (4) Rinse thoroughly with water while vacuuming until the color of this product has disappeared. Then dry with oil-free air.
 - Rinse with water for 10 sec or more. Rinse additionally with water if a large amount is applied.

[N.B.: Technical Directions and Points for Attention]

- (1) This product contains phosphoric acid as an ingredient. If this product is used near the pulp, pulp capping is recommended to prevent pulpal irritation.

- (2) To prevent deterioration in quality of material properties, do not mix this product with other etching materials.
- (3) Do not allow blood or saliva to contaminate the surface of teeth and adherend surface of restorations after treatment with this product. If contamination occurs, repeat the treatment with this product.
- (4) If the color of this product still remains after rinsing, remove the colored area with an excavator or a round bur.
- (5) When using this product for the first time or after a long period of storage, confirm the viscosity of the collected product before use. Discontinue use if excessive force is required to dispense the paste.
- (6) Be careful not to apply this product to any part of the body other than the indicated area.
- (7) Make sure that no one is around and test a small amount from the syringe to make sure that it is not clogged.
- (8) Before use, check that the needle tip is not loose or falling off, and that this product in not adhering to the fitting part of the syringe.
- (9) If a temporary bonding or sealing material is used, remove it mechanically with an ultrasonic scaler, etc., before applying this product.
- (10) When rinsing the product with water, avoid rinsing under high pressure and use a vacuum to prevent splashing of the product.
- (11) When air drying, be careful not to over dry the dentin.
- (12) Do not use abrasive pastes containing oil or fluoride, as they may interfere with the etching effect.
- (13) When using an air syringe, etc., to blow air to the tooth surface before and after applying the product, make sure that no oil or other adhesion inhibiting substance is sprayed before use

[Precautions]

- (1) Be careful of accidental ingestion by patients.
- (2) Use as soon as possible after opening the package.
- (3) Since storing with the needle tip in place may cause leakage, discard the needle tip after use and immediately attach the safety plug (the cap) securely to the syringe for storage.
- (4) Dispose of this product as a medical waste to prevent infection.

[Important Basic Cautions]

- (1) Stop using this product immediately if any signs of allergy, such as irritation or rash, appear in patients; then advise affected patients to seek medical advice.
- (2) Operators must discontinue use if any signs of irritation or rash appear, and seek medical advice.
- (3) Take care to prevent this product from adhering to the eyes, skin or clothing. In case of adhesion to the skin or clothing, wipe off immediately with an alcohol-soaked cotton swab and rinse with plenty of running water. If this product gets into the eyes, rinse immediately with plenty of running water and advise the affected patient to seek medical advice.
- (4) Wear medical gloves and eye protection while using this product to prevent it from adhering to the eyes, skin, or clothing. In case of adhesion to the skin or clothing, wipe off immediately with an alcohol-soaked cotton swab and rinse with plenty of running water. If this product gets into the eyes, rinse immediately with plenty of running water and advise the affected patient to seek medical advice.
- (5) If this product is accidentally swallowed, ask the person to rinse their mouth thoroughly with water and seek medical advice if necessary.
- (6) Do not mix this product with hypochlorite or materials and agents containing it, as harmful chlorine gas will be generated.

[Handling and Storage]

- This product must be stored at a room temperature of 1°C-30°C.
If this product is not to be used and stored for a long period, it is recommended that it be stored refrigerated (1°C-10°C).
- Store this product away from direct sunlight.
- Close the cap immediately after use to store this product.

[Note]

If a serious incident attributable to this product occurs, report it to the manufacturer shown below and the regulatory authorities of the country in which the user/patient resides.

[Expiry Date]

- ① This product must be used before the expiry date* printed on the package.
- ② The expiry date printed on the package is based on our authentication (company data).
- ③ The expiry date printed on the package is the "use before" date.
*(e.g.; EXP YYYY-MM indicates YYYY ‘year’/MM ‘month’ (last day) as the expiry date.)





1090-3 Otani, Kamibun, Kagami-cho,
Konan-shi, Kochi, 781-5451, Japan
E-Mail : contact@yamakin-gold.co.jp