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#SMT2032

# Medi-Etch Bond

## Dental Bonding Agent

### INTRODUCTION

**Medi Etch Bond** is a single-component, light-cured bonding agent enabling simultaneous treatment of both dentin and enamel using one liquid.

### II. INDICATIONS

**Medi Etch Bond** is indicated for the following uses:

- 1- Surface treatment of porcelain, - ceramics, hybrid ceramics or composite resin
- 2- Intraoral repairs of fractured crowns/ bridges made of porcelain, ceramics, hybrid ceramics or composite resin

### III. CONTRAINDICATIONS

Patients with a history of hypersensitivity to methacrylate monomers

### IV. POSSIBLE SIDE EFFECTS

Due to the coagulation of protein the oral mucosa membrane may turn slightly white when exposed to Medi Etch Bond. This phenomenon is a temporary which will disappear within a few days.

### V. INCOMPATIBILITIES

1- Avoid 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- When using hemostatics containing aluminum chloride, minimize the quantity; use caution to prevent contact with the adherent surface. Failure to do so would 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 the use of the product, remove the product and seek medical attention.

3. Use 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 the patient's eyes from splashing material.

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

Immediately wash the eye with copious amounts of water and consult a physician. Immediately wipe the area with a cotton pledget or a gauze moistened with alcohol; rinse with copious amounts of water.

5. Use caution to prevent the patient from accidentally swallowing the product.

6. Avoid looking directly at the dental curing light when curing the product.

7. Avoid using the same product dispensed into a well of the dispensing dish and the same applicator brush for different patients to prevent cross infection. Discard the applicator brush after use.

8. Wear gloves or take other appropriate protective measures to prevent the occurrence of hypersensitivity that may result from contact with methacrylate monomers.

#### 2. Handling and manipulation precautions

1. The product should not be used for purposes other than specified in [II.INDICATIONS]. 2. The use of the product is restricted to licensed dentist.

3. The product contains ethanol, a flammable substance. Do not use it near an open flame.

4. Treat appropriately in a cavity close to the pulp or accidental pulp exposure with a pulp capping agent.

5. To prevent poor performance and handling characteristic, observe the specified light curing times and other handling requirements.

6. Clean the cavity sufficiently to prevent poor bonding. If the adherent surface is contaminated with saliva or blood, wash it thoroughly and dry before bonding.

7. Use the light blocking plate to avoid exposing the material to an operating light or natural light, and use within 7 minutes after dispensing. As the volatile ethanol which is contained in the Medi Etch Bond evaporates, the viscosity increases, thereby making it difficult to apply.

8. During the application of the Medi Etch Bond to the adherent surface and the duration of leaving it in place for 10 seconds after the application, move the lighting-spot out of the mouth or turn off the light to prevent the applied Medi Etch Bond from being exposed to the operating light because the Medi Etch Bond may gelate when left under such a light. In addition, after treatment for 10 seconds, dry sufficiently as soon as possible by blowing mild air.

9. Medi Etch Bond contains ethanol and water. Dry the entire adherent surface sufficiently by blowing mild air for more than 5 seconds until the bond does not move; otherwise, the adhesion effect will be impaired. In order to dry sufficiently, adjust the air pressure according to the shape and size of the cavity and the prosthetic appliance. Use a vacuum aspirator to prevent the bond liquid from scattering.

10. Do not use Medi Etch Bond in conjunction with other bonding agents. Intermixing materials may cause a change in physical properties, including a possible decrease, from the properties expected results.

11. If the treated surface is contaminated, wash it with water, dry, or clean with alcohol, and treat again with the product.

12. If there is an adherent surface including precious metal, apply a metal adhesive primer.

13. If there is an adherent surface including uncut enamel, apply Medi Etch GEL to the uncut enamel, leave it in place for 10 seconds, wash with water, and then dry. After then, apply the product to an adherent surface.

14. When placing a dental post using Medi Etch Bond, do not use a dental core build-up material except Medi Core.

15. 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.

16. 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 is to be light-cured, it is advisable to divide the area into several sections and light-cure each section separately.

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#### 3. Storage precautions

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

2. The product must be refrigerated (2-8°C/ 36-46°F) when not in use, and should be brought to room temperature for more than 15 minutes before using. After taking out of the refrigerator, the product must be left standing until it comes to room temperature; otherwise, the excessive amount of liquid might be dispensed or the liquid might ooze after use.

3. The container should be tightly capped immediately after use to reduce the evaporation of the volatile solvent (ethanol contained in the product) . If the liquid does not flow easily from the nozzle, the nozzle may have plugged up. Do not dispense the liquid forcibly from the plugged container.

4. If the liquid may not flow easily, since it has not been used for a long term, shake the container before use.

5. Keep away from extreme heat, direct sunlight or a flame.

6. The product must be stored in proper places where only dental practitioners can access it.

### VII. COMPONENTS

Medi Etch Bond

Principal ingredients:

- 10-Methacryloyloxydecyl dihydrogen phosphate(MDP)
- Bisphenol A diglycidylmethacrylate (Bis-GMA)
- 2-Hydroxyethyl methacrylate (HEMA)
- Hydrophilic aliphatic dimethacrylate
- Hydrophobic aliphatic methacrylate
- Colloidal silica
- Sodium fluoride
- dl-Camphorquinone

- Accelerators
- Initiators
- Ethanol
- Water

### VIII. CLINICAL PROCEDURES

#### A. Standard procedure

##### A-1. Moisture control

In order to produce optimal results, avoid contamination of the treatment area with saliva or blood. A rubber dam is recommended to keep the tooth clean and dry.

##### A-2. Cavity preparations

Remove any infected dentin using caries detection material (e.g. Medi Caries Detector) as a guide and prepare the cavity in the usual manner.

##### A-3. Pulp protection

Any actual or near pulp exposure could be covered with a hard setting calcium hydroxide material. There is no need for cement lining or basing. Do not use eugenol materials for pulp protection.

##### A-4. Acid etching of uncut enamel

If there is an adherent surface including uncut enamel, apply Medi Etch GEL (40% phosphoric acid gel) to the uncut enamel, leave it in place for 10 seconds, wash with water, and then dry.

##### A-5. Application of Medi Etch BOND

1. Dispense the necessary amount of **Medi Etch BOND** into a well of the dispensing dish immediately before application.

2. Apply **Medi Etch BOND** to the entire cavity wall with the applicator brush. Leave it in place for 10 seconds. Use caution not to allow saliva or exudate to contact the treated surfaces.

3. Dry the entire cavity wall sufficiently by blowing mild air for more than 5 seconds until the bond does not move. Use a vacuum aspirator to prevent the bond liquid from scattering. 4. Light-cure **Medi Etch BOND** for 10 seconds with a dental curing unit (see table "Dental curing unit")

Table: Dental curing unit

| Light source | Wavelength range /nm | Light intensity/mW/cm <sup>2</sup> |
|--------------|----------------------|------------------------------------|
| Halogen Lamp | 400 - 550            | Greater than 500                   |
| Blue LED     |                      |                                    |

Evaluated according to ISO 10650-1 &ISO 10650-2.

[Caution] Federal (U.S.A.)law restricts this device to sale by or on the order of a licensed dentist.

[WARRANTY]

**SwissMediTec GmbH.** will replace any product that is proven to be defective. **SwissMediTec GmbH.** 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.



Reference Number



Keep away from sunlight



Refer to instruction manual



Keep Dry



Storage temperature range



Expiry date



Date of Manufacture



Manufactures address



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