

EZ Bond Universal

Dental Adhesive



2023. 3. 17. DM-231-0 | MADE IN KOREA



Manufacturer

META BIOMED CO., LTD.

270, Osongsaengmyeong 1-ro,
Osong-eup, Heungdeok-gu, Cheongju-si,
Chungcheongbuk-do, Republic of Korea

Tel +82-43-216-0433

Fax +82-43-217-1988

E-Mail info@meta-biomed.com

www.meta-biomed.com

GENERAL DESCRIPTION

EZ Bond Universal, manufactured by Meta Biomed, is classified as a Resin tooth bonding agent (21 C.F.R. 8872.3200). EZ Bond Universal is a single-bottle solution. Depending on the indication, the adhesive can be used for direct and indirect restorations with light cured composites in a "self-etching" procedure, "total-etching" procedure or "selective-etching" procedure. EZ Bond Universal is methacrylate-based restoratives, cement and sealant materials to dentin, enamel, glass ionomer and various indirect restorative substrates (glass ceramics, alumina and zirconia) without an extra primer step.

INDICATION FOR USE

- All classes of fillings (according to Black) with light-curing composite or compomer filling materials
- Repair of composite resin or compomer fillings
- Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer
- Protective varnish for glass ionomer fillings

OPERATION OR INSTRUCTION

1. Preparations Before Use

- #### 1.1 Preparation of Caries and Root Procedure
- Remove residue from procedure preparation by spraying water.
 - Lightly dry the root or caries with air without moisture and oil 2-3 times or remove the moisture with a cotton ball. (There may be sensitivity after the procedure if too dry)
- #### 1.2 Tooth Enamel Unprepared for Procedure
- As a common method, clean the enamel (polishing cream or powder blasting) and spray water to clean.
 - Then the enamel is etched (35% phosphoric acid etching gel) and clean with water.
- #### 1.3 Etching Tooth Surface (Optional)
- High adhesive effect can be seen by selective enamel etching or full etching.
 - Apply the 35% phosphoric acid etching gel to enamel and wait for 15 seconds to be effective.
 - Spray water to wash and lightly dry with air with no moisture and oil or wipe the eater with cotton ball. (There may be sensitivity after the procedure if too dry)
- #### 1.4 Measure Adhesive
- Open the cap by rotating it counter-clockwise.
 - Drop 1-2 drops of adhesive into the container. (close the cap after use to minimize evaporation of solvent.)

2. Instructions for Use

2.1 Direct Restorations

- Self-Etching Technique: After cavity preparation, clean with water and remove the remaining moisture. (Do not dry too much and leave some moisture.)
- Total-Etching Technique: After prepping the cavity, clean with water. Etch the dentin and enamel layer for 15 seconds. Completely wash with water and remove any remaining moisture. (Do not dry too much and leave some moisture.)
- (1) Drop 1-2 drops of EZ Bond Universal into a clean container.
 - (2) Apply EZ Bond Universal once using a micro brush. (Rub for about 20 seconds when applying.)
 - (3) Remove remaining solvent by blowing air for 10 seconds with the air gun. After air drying, check if the surface has an overall uniform shine. (If the shine is not uniform, apply another layer and air dry.)
 - (4) Light-cure for 10 seconds. (Light-curing unit wavelength: 420~500nm, Intensity of light: more than 450mW/cm²)
 - (5) Continue the adhesion of restoration.

2.2 Indirect Restorations

- **Tooth Preparation**
- Self-Etching Technique: After cavity preparation, clean with water and remove the remaining moisture. (Do not dry too much and leave some moisture.)
- Total-Etching Technique: After prepping the cavity, clean with water. Etch the dentin and enamel layer for 15 seconds. Completely wash with water and remove any remaining moisture. (Do not dry too much and leave some moisture.)
- (1) Drop 1-2 drops of EZ Bond Universal into a clean container.
 - (2) Apply EZ Bond Universal using a micro brush. (Rub for about 20 seconds when applying.)
 - (3) Remove remaining solvent by blowing air for 10 seconds with the air gun. After air drying check if the surface has an overall uniform shine. (If the shine is not uniform, apply another layer and air dry.)
- NOTE:** EZ Bond Universal can be thinly applied with the solvent which does not impact the adhesion of restorations.
- (4) After light-curing for 10 seconds, proceed with adhesion.

■ **Priming of Metal, Zirconia, Alumina, composite and Post Restorations:**

- (1) Process the surface of prosthetic restoration as instructed by the manufacturer or factory. (ex: Particle abrasion)
- NOTE:** Do not clean the surface using Etchant before applying the adhesive.
- (2) Apply EZ Bond Universal and remove the remaining solvent with air then light-cure for 10 seconds.
- NOTE:** Light-curing is recommended for optimal solidity and durability of EZ Bond Universal.

■ **Priming of Porcelain (silica-based) or Lithium Disilicate Restorations:**

- (1) Various ceramics out in the market require different methods of surface processing. Make inquiries to the factory or manufacturer on the proper processing of inside.
 - (2) Apply EZ Bond Universal and remove the remaining solvent with air then light-cure for 10 seconds.
- NOTE:** Light-curing is recommended for optimal solidity and durability of EZ Bond Universal. Use silane if light-curing is not effective. Silane provides effective durability of adhesiveness and longevity on glass ceramics.

2.3 Desensitization/Sealing of Tooth

- **Prepared tooth surface**
- Self-Etching Technique: After cavity preparation, clean with water and remove the remaining moisture. (Do not dry too much and leave some moisture.)
- Total-Etching Technique: After prepping the cavity, clean with water. Etch the dentin and enamel layer for 15 seconds. Completely wash with water and remove any remaining moisture. (Do not dry too much and leave some moisture.)
- (1) Drop 1-2 drops of EZ Bond Universal into a clean container.
 - (2) Apply EZ Bond Universal using a micro brush. (Rub for about 20 seconds when applying.)
 - (3) Remove remaining solvent by blowing air for 10 seconds with the air gun. After air drying check if the surface has an overall uniform shine. (If the shine is not uniform, apply another layer and air dry.)
 - (4) After light-curing for 10 seconds, proceed with temporary restoration.
 - (5) Proceed with temporary restoration.

■ Uncut tooth surface

- (1) Rub to clean the root surface and uncut tooth by using Pumice.
- (2) Rinse with warm water and remove any remaining moisture.
- (3) Drop 1-2 drops of EZ Bond Universal into a clean container.
- (4) Apply EZ Bond Universal using a micro brush. (Rub for about 20 seconds when applying.)
- (5) Remove remaining solvent by blowing air for 10 seconds with the air gun. After air drying check if the surface has an overall uniform shine. (If the shine is not uniform, apply another layer and air dry.)
- (6) Light-cure for 10 seconds.
- (7) Remove oxygen-inhibited layer with cotton pellet or gauze soaked with alcohol.

2.4 Intraoral Repairs

- (1) Process (roughly) the surface to be bonded. Then clean with water and air dry.
- (2) Process the surface of any porcelain or lithium disilicate using hydrogen fluoride for a specific time period. Apply a silane primer such as porcelain primer for optimal adhesiveness and durability.
- (3) Drop 1-2 drops of EZ Bond Universal into a clean container.
- (4) Apply one layer of EZ Bond Universal to the treatment area. Then remove the solvent using the air gun and light-cure for 10 seconds.
- (5) Proceed with composite buildup and final touches.

2.5 Protective Varnish for Glass Ionomer Fillings

EZ Bond Universal protects the surface of cement and restoration for glass ionomer base from moisture (humidity), dryness, and contamination from saliva. (After adhesion of restoration).

Tooth Preparation:

- (1) Restore the cement and restoration material on the glass ionomer base as instructed by the manufacturer.
- (2) Drop 1-2 drops of EZ Bond Universal into a clean container.
- (3) Apply EZ Bond Universal using a micro brush. (Rub for about 10-15 seconds when applying.)
- (4) Remove remaining solvent by blowing air for 10 seconds with the air gun.
- (5) Light-cure for 10 seconds.
- (6) Remove oxygen-inhibited layer with cotton pellet or gauze soaked with alcohol.

HOW TO STORE AND CONTROL AFTER USE

- 1) Micro brush is disposable and should be disposed of after use.
- 2) Wipe the opening of the bottle with gauze and close with a cap.
- 3) Immediately close the bottle with the cap after use to minimize evaporation.
- 4) Store in a dry and cool area.
- 5) Store where it will not be exposed to direct sunlight.
- 6) Do not store near a firearm.

PRECAUTIONS FOR USE

1. General Precautions

- 1.1 Wear proper gloves, masks, and protective glasses.
- 1.2 The product cannot be prescribed for internal use.
- 1.3 Use in a well-ventilated place and avoid inhaling the vapor.
- 1.4 This product is a light-curing material and should avoid being exposed to general lights.
- 1.5 Unpolymerized material can cause skin irritation to some users and patients. Avoid skin contact and if skin contact occurs, thoroughly wash with soap and water.

1.6 When using the light-curing device, closely place the device as possible for polymerization. If polymerizing a large area, divide the area into sections to thoroughly polymerize each section.

1.7 If the polymerization device has an insufficient intensity of light (below 450 mW/cm²), it is difficult to reach thorough adhesiveness. Check the intensity for use.

1.8 Check the expiration date on the label.

2. Warnings

- 2.1 Do not fill this product to the root canal.
- 2.2 This product is prohibited for other purposes than its intended use and by a non-specialist.
- 2.3 Avoid contact with this product as it may irritate the skin, eyes, and oral mucosa. If contact occurs, thoroughly wash with water and seek medical advice.
- 2.4 Do not use this product to patients with a medical history of hypersensitivity such as rashes and dermatitis.
- 2.5 Do not use on patients allergic to ingredients of this product.
- 2.6 Do not use this product on pregnant women or lactating women as it has not been tested.

3. Precautions in Application

- 3.1 Use after installing the rubber dam on the patient's mouth before the procedure.
- 3.2 Be careful for the adhesive to not come in contact with oral mucosa.
- 3.3 If dental treatment was done by using a material that contains ZOE, clean the treatment area to use the adhesive.

SIDE EFFECTS

Not known yet

CONTRAINDICATIONS

Do not use on patients with a severe allergic reaction to methacrylate resin.

STORAGE

1. Store in a well-ventilated area away from direct sunlight.
2. Store EZ Bond Universal at temperature between 2 to 25°C / 35.6 to 77°F
3. Do not use after the expiration date.

PACKAGING

It is packaged in a container made with polypropylene copolymer which is packaged in a paper box.

PACKAGING UNIT

EZ Bond Universal(5g), Micro brush 10ea, IFU 1ea

EXPIRY DATE

2 years from the date of production

SYMBOLS

- Manufacturer
- Date of manufacture
- Batch Code
- Use By
- Consult instructions for use
- Keep away from sunlight
- Temperature limitation

Rx Only Caution: Federal law restricts this device to sale by or on the order of a dentist

| 품명 | EZ Bond Universal IFU(en)(Rx Only) | | |
|---------------|------------------------------------|--------------|--------------|
| 서식번호 | DM-231-0 | Revised Date | Explications |
| 치수 | 198X205 | 2023.03.17 | 신규등록 |
| 용지재질 | 모조 45g | | |
| 작업자 | | | |
| tinting Color | | | |