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Identification Number: 230AABZX00076000

Controlled Medical Device - Dental Adhesive-for Coronal Dentine
Dental Adhesive for Dental Ceramics
Dental Adhesive for Dental Metal

TMR-AQUA BOND 0

[Indications]

Adhesive for direct light-cured composite restoration

[Contraindications and Prohibitions]

- DO NOT USE THIS PRODUCT ON PATIENTS WHO HAVE A HISTORY OF ALLERGY SUCH AS IRRITATION TO THIS PRODUCT OR METHACRYLIC ACID AND SIMILAR ACIDS OR METHACRYLATE MONOMER AND ETHANOL.
- DO NOT REUSE DISPOSABLE DISPENSING DISHES AND DISPOSABLE APPLICATOR BRUSHES.

[Shape, Composition and Principles]

This product consists of the following items and contains the ingredients below:

Constituent Name	State	Ingredients
Bond	Liquid	distillated water, methacrylate monomer, phosphate monomer, carboxylic monomer, photopolymerization initiator, ethanol, thickener, etc.
Accessories	-	disposable dispensing dish, disposable applicator brush

Principle:

This product is a self-etching, light-curing, single-component adhesive for enamel and dentine.

When this product is applied to the tooth surface, the tooth substance is demineralized, and at the same time the monomer component penetrates into the tooth substance, then polymerizes by light curing and adheres to the tooth substance.

In cases where the adherend is made of zirconia ceramics, the adhesive monomer contained in this product improves the surface of dental restorations and adheres by light curing. In cases where the adherend is made of metal, the adhesive component contained in this product improves the surface of dental restorations and adheres by light curing. In cases where the adherend is made of dental porcelain, or resin material containing inorganic filler, use a primer for ceramics, (e.g., Multi Primer Liquid). The adhesive component contained in the primer improves the surface of dental restorations and adheres by light curing.

[Intended Use and Effects/Efficacy]

[Intended Use]

This product is intended to be used as an adhesive for cavities including dentine areas and as an adhesive for chipped teeth and artificial crowns or restorations and devices made of dental ceramics and metal.

[Instructions for Use]

[Materials for use in combination with this product]

Resin-based dental restorative material: TMR-Z Fill 10. etc.

Dental bonding material for dental ceramics: Multi Primer Liquid, etc.

Dental etching agent: Multi Etchant, etc.

[Cure time]

The cure time is as given in the below table.

The cure time needs to be adjusted depending on the amount of light and the wavelength of the light.

When using this product under clinical conditions, refer to the manual provided with the device used for information on appropriate light levels for curing.

Curing Time of This Product

Dental light curing unit (Light Intensity)	Curing Time
Halogen	10 sec. and over
LED whose light intensity is 300 mW/cm ² and over.	10 sec. and over
LED whose light intensity is 2400 mW/cm ² and over.	3 sec. and over

- Halogen Lamp

Dental curing light which has halogen lamp as a light source, and which emits an effective wavelength of 400-515 nm, and with light intensity of 300 mW/ cm²and over.

- LED Curing Light

Dental curing light with blue LED as a light source; its emission spectrum peak top is 450-480 nm and it emits an effective wavelength of 400-515nm.

[Instructions]

- Filling restoration with composite resin

(1) Cavity Preparation

Perform cavity preparation in accordance with normal practice, clean and dry. If cavity preparation is to be done significantly near to dental pulp exposure area, perform pulp capping procedure in accordance with normal practice. To prevent contamination with blood and saliva, exclude moisture with rubber dam is recommended.

(2) Cleaning the Adherend Surface

Apply dental etching agent on the adherend surface then wash and dry in accordance with the instructions as necessary.

(3) Applying and Drying

Place this product on a disposable dispensing dish and apply a sufficient amount of the product sufficiently to the whole inside of the cavity with a disposable applicator brush. Perform air-blowing with vacuuming, in order to prevent scattering. At this point, spread the adhesive layer into a thinner layer and dry the whole adherence surface sufficiently.

(4) Light Curing

After drying, cure with a dental light curing unit.

(5) Filling Resin-based Dental Restorative Material

Fill resin-based dental restorative material into the cavity and light cure with a dental light curing unit. Follow the instructions for use of the resin-based dental restorative material. After light curing, correct the shape and polish in accordance with normal practice.

Prior to use, carefully read the instruction manual.

• Repairing fracture or wear of crown restorations made of zirconia ceramics and metal

- (1) **Excluding Moisture**
Exclude moisture with rubber dam as necessary.
- (2) **Surface Roughening of the Adherend Surface**
Roughen surface with diamond point, wash with water and dry. Shape bevel at margin area as necessary.
- (3) **Cleaning the Adherend Surface**
Apply dental etching agent on the adherend surface then wash and dry in accordance with the instructions as necessary.
- (4) **Applying and Drying**
Place this product on a disposable dispensing dish and apply a sufficient amount of the product to the whole adherend surface with a disposable applicator brush. Perform air-blowing with vacuuming, in order to prevent scattering. At this point, spread the adhesive layer into a thinner layer and dry the whole adherence surface sufficiently.
- (5) **Light Curing**
After drying, cure with a dental light curing unit.
- (6) **Filling Resin-based Dental Restorative Material**
Fill resin-based dental restorative material into the adherend surface and light cure with a dental light curing unit. Follow the instructions for use of the resin-based dental restorative material. After light curing, correct the shape and polish in accordance with normal practice.

• Repairing fracture or wear of crown restorations made of dental porcelain, or resin material containing inorganic filler

- (1) **Excluding Moisture**
Exclude moisture with rubber dam as necessary.
- (2) **Surface Roughening of the Adherend Surface**
Roughen surface with diamond point, wash with water and dry. Shape bevel at margin area as necessary.
- (3) **Cleaning the Adherend Surface**
Apply dental etching agent on the adherend surface then wash and dry in accordance with its instructions as necessary.
- (4) **Applying and drying adhesive for dental ceramics**
After cleaning and drying, apply adhesive for dental ceramics on the adherence surface immediately and dry for about 60 sec.
- (5) **Applying and Drying**
Place this product on a disposable dispensing dish and apply a sufficient amount of the product to the whole adherend surface with a disposable applicator brush. Perform air-blowing with vacuuming, in order to prevent scattering. At this point, spread the adhesive layer into a thinner layer and dry the whole adherence surface sufficiently.
- (6) **Light Curing**
After drying, cure with a dental curing light unit.
- (7) **Filling Resin-based Dental Restorative Material**
Fill resin-based dental restorative material into the adherend surface and light cure with a dental light curing unit.
Follow the instructions for use of the resin-based dental restorative material. After light curing, correct the shape and polish in accordance with normal practice.

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

- (1) For light-curing this product, use a dental curing light unit with LED or halogen lamp which emits an effective wavelength of 400-515nm. Since curing time needs to be adjusted depending on the amount of light and the wavelength of the light, please follow the condition in the table, "Curing Time of This product".
 - In cases where other type of medical curing equipment is to be used, or if you have any questions about curing units, please feel free to contact us.
- (2) In cases where this material is used for burr-free cut enamel, clean the surface of enamel, apply etching agent in accordance with the instructions for use, wash and then dry.
- (3) If cavity preparation is to be done significantly near to dental pulp exposure area, perform pulp capping procedure with dental pulp capping material, before applying this material.
- (4) Do not use eugenol or related products for protecting pulp and temporary sealing as it may hinder curing and bonding.
- (5) This product contains water and alcohol. If drying is not sufficient, adhesive strength will be lowered. The adherend surface must be completely dry.
- (6) Close the cap immediately after use as this product contains volatile constituents.
- (7) Do not mix this product with other adhesive products for dentine, metal, ceramics or resin, in order to prevent deterioration in quality of material properties.
- (8) If this product is stored in a refrigerator, allow this product to reach room temperature before using it.
- (9) Maintain the cleaned or processed adherence surface with this product or Multi Primer Liquid so as to prevent it being contaminated by blood or saliva. If it is contaminated, proceed again from the acid treatment step.
- (10) Since this product contains volatile constituents, advise the patient to breathe through the nose.

[Precautions]

- ① This product contains ethanol which is a combustible substance. Do not use this product in proximity to fire.
- ② Use this product in the place where adequate ventilation is done several times in an hour.
- ③ Do not use this product outside the scope of recommended indications, effects or efficacy.
- ④ To prevent cross infection, do not reuse disposable accessories.
- ⑤ Only adequately certified personnel should handle this product.

[Important Basic Cautions]

- ① Stop using this product immediately if any signs of allergy, such as irritation or rash, appear in patients. If symptoms persist, advise to seek medical advice.
- ② Operators must discontinue use if any signs of irritation or rash appear. If symptoms persist, seek medical advice.
- ③ Take action to prevent eye and skin contact or adhesion to clothes. In case of skin contact or adhesion to clothes, wipe with an alcohol-soaked cotton swab, and wash with plenty of running water. In case of eye contact, immediately rinse out the eye with plenty of running water, and consult a physician.
- ④ Pay attention to prevent adhesion of this product to positions excepting affected parts. In case of adhesion, immediately wipe with a cotton swab, and wash with water enough after operating. The adhesion point might turn white but it is evanescent.
- ⑤ Take action to prevent eye and skin contact or adhesion to clothes such as wearing medical plastic gloves and safety goggles. In case of skin contact or adhesion to clothes, wipe with an alcohol-soaked cotton swab, and wash with plenty of running water. In case of eye contact, immediately rinse out the eye with plenty of running water, and consult a physician.

[Handling and Storage]

- This product must be stored in a refrigerator at a temperature of 1-10°C.
- Avoid direct sunlight and fire. Do not store large quantities of product in the same storage area.
- Close the cap immediately and store after use.
- Equip work and storage areas with fire extinguishers.
- Keep out of reach of personnel other than dental staff.

[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.
- ③ The expiry date printed on the package refers to use expiry date.
*(e.g.: EXP YYYY-MM indicates YYYY 'year'/MM 'month' (last day) as the expiry date)

[Package]

- [Set Package]
- TMR-AQUA BOND 0 set
TMR-AQUA BOND 0 (5 ml): 1 bottle
Accessories: Disposable applicator brush x 50
Disposable dispensing dish x 25
 - 2 pcs Pack
TMR-AQUA BOND 0 (5 ml): 2 bottle

[Single Package]

- TMR-AQUA BOND 0 (5 ml): 1 bottle

[Accessory/ Single Item]

- Disposable applicator brush x 50
- Disposable dispensing dish x 50

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