

December 1, 2023 (Revision 7)

Identification Number: 226AABZX00133000Controlled Medical Device - Dental Adhesive for Coronal Dentine
Dental Adhesive for Dental Ceramics, Dental Adhesive for Dental Metal

iGOS-BOND

[Product description]

[Intended purpose]

This product is intended to be used as an adhesive agent for cavities including dentine, chipped tooth and artificial crowns. In cases where Multi Primer Liquid is used in combination with this product, this product is intended to be used as an adhesive agent for dental restorations or devices made of dental porcelain, or for metal restorations or devices.

※Please check the following as necessary

- Filling restoration with dental filling composite resin cured by light
- Repairing fracture or wear of crown restorations made of zirconia ceramics, dental porcelain, or resin material containing inorganic filler, and metal, used in combination with Multi Primer Liquid

[Indications]

- Direct anterior and posterior restoration (excluding root canal filling)

[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]

Repair a patient's teeth and artificial crowns by applying to intraoral cavities and chipped / damaged teeth.

[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	ethanol, distilled water, methacrylate monomer, phosphate monomer, carboxylic monomer, photopolymerization initiator, etc.
Accessories	-	disposable dispensing dish, disposable applicator brush

Principle:

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

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

[Product Specifications]

Properties	Specification	Test method
Bovine Enamel	5MPa and over	Based on ISO/TS 11405: 2003 Tensile bond strength* ²
Bovine Dentine	5MPa and over	
Metal* ¹	15MPa and over	
Zirconia Ceramics* ¹	10MPa and over	
Porcelain* ¹	17MPa and over	

*1: Multi Primer Liquid, dental bonding agent for dent

*2: Resin-based Dental Restorative Material is used as a test piece.

[Instructions for Use]

[Materials for use in combination with this product]

Resin-based dental restorative material: e.g. "iGOS" or "TMR-Z Fill 10."

Dental bonding material for dental ceramics: e.g. "Multi Primer Liquid"

Dental etching agent: e.g. "Multi Etchant" etc.

[Dental Curing Light]

(1) 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/cm² and over.

(2) 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 with the light intensity is 300 mW/cm² and over.

[Cure time]

The cure time is as given in the 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, please refer to the manual provided with the device used for information on appropriate light levels for curing.

Cure Time of This Product

Dental Curing Light Irradiator	Halogen or LED Irradiator
Light-Curing Time	About 10 sec.

[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) Application

Place this material on a disposable dispensing dish and apply this material on whole inside of cavity with a disposable applicator brush. After leaving for about 20 sec., perform suction with a vacuuming device in order to prevent scattering while air-blowing sufficiently. At this point, spread the bond layer into a thinner layer and dry a whole adhesive surface sufficiently.

(3) Light Curing

After drying, cure with curing light.

(4) Filling Resin-based Dental Restorative Material

Fill Resin-based Dental Restorative Material into the cavity and light cure with a dental light curing machine. Please follow the manual. 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, dental porcelain, or resin material containing inorganic filler and metal
- (1) Excluding Moisture
Exclude moisture with rubber dam as necessary.
- (2) Surface Roughening of Adherend
Roughen surface with diamond point, wash with water and dry. Shape bevel at margin area as necessary.
- (3) Acid Treatment of Adherend
Apply etching agent containing phosphoric acid in accordance with the instructions for use, wash with water and dry.
- (4) Applying Multi Primer Liquid and Drying
After washing and drying, apply Multi Primer Liquid immediately and air-blow for about 10 sec.
- (5) Applying This Product and Drying
Take out this product on the disposable dispensing dish and apply it thoroughly to the entire adherend surface with a disposable applicator brush. After about 20 sec., air-blow well by vacuuming to prevent scattering. At this step, dry entire surface thoroughly, spreading the bonding layer thinly.
- (6) Light Curing
Light cure with dental light curing unit after drying.
- (7) Filling Composite Resin
Fill dental filling composite resin cured by light on adherend surface and light cure. Refer to the instructions for the dental composite resin. 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 light curing unit with LED or halogen lamp which emits an effective wavelength of 400-515nm. Since cure time needs to be adjusted depending on the amount of light and the wavelength of the light, please follow the condition in the table, "Cure 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 non-bur 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 calcium hydroxide agent 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 adhesion 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 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 adherend 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 combustible. 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.
- ⑥ 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. 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.

[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.
- 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]

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