

December 1, 2023 (Revision 9)

Identification Number: 226AABZX00132000

Controlled Medical Device - Resin-based Dental Restorative Material

IGOS**[Product description]**

[Intended purpose]

This product is intended to be used for restoration of intraoral cavities and chipped / damaged teeth, except for pulp. It is also intended to be used for repairing artificial crowns.

[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.**
• **DO NOT REUSE NEEDLE.**

[Shape, Composition and Description]

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

Type	State	Components	Inorganic Filler Content Rate
Universal	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: particle diameter <20 μ m), pigments, etc.	Approximately 55 vol%
Flow	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: particle diameter <20 μ m), pigments, etc.	Approximately 42 vol%
Low Flow	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: particle diameter <20 μ m), pigments, etc.	Approximately 45 vol%

Universal: 16 Shades: A1, A2, A3, A3.5, A4, A5, B1, B2, B3, C2, C3, D2, OA2, OA3, BW, E

Flow: 13 Shades: A1, A2, A3, A3.5, A4, A5, OA2, OA3, OA3.5, OA4, OA5, BW, E

Low Flow: 13 Shades: A1, A2, A3, A3.5, A4, A5, OA2, OA3, OA3.5, OA4, OA5, BW, E

Principles: This material is Resin-based Dental Restorative Material and is cured by visible light.

[Product Specifications]

Test method: ISO 4049

It is applicable for the restoration of occlusal surface. The specification which is light cured inside mouth is applied.

Items	Specification
Increment Depth	Opaque 1.0 mm and over
	Others 1.5 mm and over
Flexural Strength	80 MPa and over
X-ray contrast	Positive

[Instructions for Use]

[Materials for use in combination with this product]

Dental Adhesive: e.g. "TMR-AQUA BOND 0" or "iGOS-BOND"

[Dental Curing Light]

(1) Halogen Lamp

Dental curing light which has halogen lamps as a light source, and which emits an effective wavelength of 400-515 nm, and with light intensity of 400 mW/cm² and over.

(2) LED Light-Curing

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. The light intensity is 1000 mW/cm² and over.

[Cure time and Increment Depth]

The cure time and the increment depth are 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 you are using for information on appropriate light levels for curing. Also, please refer to the following table and confirm the cure time and the increment depth depending on your curing unit before using this product for clinical cases :

Cure Time and Increment Depth Table

Dental Curing Light Irradiator (Light Intensity)	Curing Time	Shade and Increment Depth	
		Opaque	Others
Halogen	20 sec.	1.0mm and over	1.5mm and over
LED	10 sec.		

※It is recommended cure time is 20 sec. in case of using LED curing light which emits an effective wavelength of 400-515nm and the light intensity is 1000 mW/cm² and under.

[Instructions]

(1) Anterior and Posterior Restorations

① Cleaning of tooth surface

Remove plaque and clean the surface of the tooth where restoration is needed.

② Selecting a shade

Select a shade for the restoration using a shade guide.

③ Cavity Preparation

Remove dental caries and shape cavity in accordance with normal practice.

④ Exclusion of moisture and pulp protection

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

⑤ Bonding treatment

Perform bonding treatment with dental adhesive for coronal dentine, following the instructions.

⑥ Filling and curing

Fill this product into the cavity and light cure following the "Cure Time and Increment Depth Table." In cases where a cavity is deep, refer to the "Cure Time and Increment Depth Table" and repeat filling and curing steps. In cases where Flow and Low Flow are used, cover the whole syringe with a protective cover such as plastic film to avoid contact with saliva and blood and to prevent cross infection.

⑦ Corrections and polishing

After curing, correct the shape in accordance with normal practice and polish with a silicone point or etc.

(2) Repairing Crown Restoration and Fractured Composite Resin

① Preparing surface and coupling treatment by silane

Make the restoration surface rough with diamond points etc. and create a bevel at the margin area if needed. Then prepare restoration area following the instructions for primer and bonding.

② Concealing Shade

In cases where concealing shade is needed, apply Opaquer thinly and cure following the instructions for the Opaquer.

③ Filling and curing

Take out this material and fill in the cavity or build-up, then cure with a curing light.

④ Finishing and polishing

After curing, correct the shape in accordance with normal practice and polish with a silicone point or etc.

Prior to use, carefully read the instruction manual.

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

- ① In cases where Flow and Low Flow are used, remove the syringe cap and attach the needle tip tightly.
- ② Cure time needs to be adjusted depending on the amount of light and the wavelength of the curing unit. When using this product under clinical conditions, please refer to the manual provided with the device you are using for information on appropriate light levels for curing. Also, please refer to the above table and confirm the cure time and the increment depth depending on your curing unit before using this product for clinical cases.
- ③ Do not use surgical cotton wool which contains too much alcohol to remove this product from a needle tip or syringe. This causes alcohol to be inserted from the tip, and the material will be diluted inside of the syringe; the proper performance may not be exhibited. Squeeze off excess alcohol from the surgical cotton wool and then use it.
- ④ Refer to the "Cure Time and Increment Depth Table" and confirm the cure time and the increment depth depending on your curing unit before using this product.
- ⑤ In cases where a cavity is deep, refer to the "Cure Time and Increment Depth Table" and repeat filling and curing steps.
- ⑥ Close the cap promptly and tightly after picking this product. In case of using Universal type, half-turn the handle in a counterclockwise direction to release residual pressure.
- ⑦ Since this product is cured by ambient light, it should be protected by a shade cover or used up quickly when this material is in use on a pallet or mixing paper.
- ⑧ Do not mix this product with other products, in order to prevent deterioration in quality of material properties.
- ⑨ In cases where Flow and Low Flow are used, be careful to prevent air bubbles being entrapped in the material, as this can easily happen.
- ⑩ If this product is stored in a refrigerator, leave this product at room temperature for several minutes before using it in order to prepare for use.
- ⑪ Increment depth is affected by the irradiation capacity of the curing light; regular maintenance, such as cleaning and replacing lamps, is needed.
- ⑫ Since handling time of this product will be shortened by use of a shadowless lamp, turning off or light reduction of the lamp as required is necessary during filling and shaping.

[Precautions]

- ① This product is combustible. Do not use or leave this product in proximity to fire.
- ② Wear safety goggles to protect the eyes and do not look directly at the curing light during curing.
- ③ When polishing cured product, use a suction device and anti-dust mask as approved by your local public safety agency in order to avoid inhaling dust.
- ④ If cavity preparation is to be done significantly near to dental pulp exposure area, perform pulp capping procedure in accordance with normal practice.
- ⑤ Do not use eugenol or related products as it may hinder curing and bonding.
- ⑥ Handle carefully to prevent accidental ingestion of this material.
- ⑦ To prevent cross infection, do not use same needle tip and applicator for different patients and do not reuse them.
- ⑧ Do not use this product in combination with other products.
- ⑨ Do not use this product outside the scope of recommended indications, effects or efficacy.
- ⑩ Only adequately certified personnel should handle this product.
- ⑪ 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, seek medical advice.
- ② Operators must discontinue use if any signs of irritation or rash appear. If symptoms persist, seek medical advice.
- ③ In order to avoid irritation, pay attention to prevent adhesion of this product to oral soft tissue or to skin. In case of oral soft tissue contact or skin contact, wipe with an alcohol-soaked cotton swab, and wash with plenty of water. In case of eye contact, immediately rinse out the eye with plenty of running water, and consult a physician.
- ④ Wear plastic gloves and safety goggles to prevent adhesion of this product to skin. In case of skin contact, 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.

[Other Cautions]

The restoration area may be stained and plaque-adherent depending on patients' dietary habits. Advise on daily oral cleaning.

[Handling and Storage]

- ① This product must be stored at a room temperature of 4-25°C.
- ② Do not store large quantities of product in the same storage area.
- ③ Equip work and storage areas with fire extinguishers.
- ④ 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]

[Single Item]

•Universal 4 g (2 ml): 16 Shades:

A1, A2, A3, A3.5, A4, A5, B1, B2, B3, C2, C3, D2, OA2, OA3, BW, E

•Flow 2.6 g (1.5 ml): 13 Shades:

A1, A2, A3, A3.5, A4, A5, OA2, OA3, OA3.5, OA4, OA5, BW, E

Accessory: needle tips x 10/ Shade

•Low Flow 2.6 g (1.5 ml): 13 Shades

A1, A2, A3, A3.5, A4, A5, OA2, OA3, OA3.5, OA4, OA5, BW, E

Accessory: needle tips x 10/ Shade

[Accessory/ Single Item]

•Needle tips: x 20

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