Identification Number: 226AABZX00132000

Controlled Medical Device · Resin-based Dental Restorative Material

iGOS

[Indications]
Direct anterior and posterior restoration (excluding root canal filling)

[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:

<table>
<thead>
<tr>
<th>Type</th>
<th>State</th>
<th>Components</th>
<th>Inorganic Filler Content Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal</td>
<td>Paste</td>
<td>methacrylate monomer, inorganic fillers (silica, alumina, and zirconia; particle diameter &lt;20μm), pigments, etc.</td>
<td>Approximately 55 vol%</td>
</tr>
<tr>
<td>Flow</td>
<td>Paste</td>
<td>methacrylate monomer, inorganic fillers (silica, alumina, and zirconia; particle diameter &lt;20μm), pigments, etc.</td>
<td>Approximately 42 vol%</td>
</tr>
<tr>
<td>Low Flow</td>
<td>Paste</td>
<td>methacrylate monomer, inorganic fillers (silica, alumina, and zirconia; particle diameter &lt;20μm), pigments, etc.</td>
<td>Approximately 45 vol%</td>
</tr>
</tbody>
</table>


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.

<table>
<thead>
<tr>
<th>Items</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increment Depth</td>
<td>Opaque 1.0 mm and over</td>
</tr>
<tr>
<td></td>
<td>Others 1.5 mm and over</td>
</tr>
<tr>
<td>Flexural Strength</td>
<td>80 MPa and over</td>
</tr>
<tr>
<td>X-ray contrast</td>
<td>Positive</td>
</tr>
</tbody>
</table>

[Intended Use and Effect / Efficacy]
This product is intended to be used for restoration of intracoronal cavities and chipped / damaged tooth, except for pulp. It is also intended to be used for contour restoration of tooth crown separation and repairing artificial crowns.

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.
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.

[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.

[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 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

• 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: Single Item]

• Needle tips: x 20