Identification Number: 222AABZ00121000
Controlled Medical Device · Composite Resin for Crowns and Bridges

**TWiNY**

**[Indications]**

Metal reinforced crowns and bridges, or metal free restorations such as jacket crowns, veneer, inlays and onlays, and implant superstructures.

**[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 SERIES OR METHACRYLATE MONOMER.

**[Shapes, Composition and Principles]**

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

<table>
<thead>
<tr>
<th>Item</th>
<th>State</th>
<th>Components</th>
<th>Inorganic Filler Content Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opaque Resin Paste</td>
<td>methacrylate monomer, inorganic fillers (silica particle diameter &lt;50μm), pigments, etc.</td>
<td>Approximately 37 vol%</td>
<td></td>
</tr>
<tr>
<td>Body Resin Paste</td>
<td>methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: particle diameter &lt;25μm), pigments, etc.</td>
<td>Approximately 36 vol%</td>
<td></td>
</tr>
<tr>
<td>Body Resin Flow Paste</td>
<td>methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: particle diameter &lt;15μm), pigments, etc.</td>
<td>Approximately 48 vol%</td>
<td></td>
</tr>
<tr>
<td>Stain</td>
<td>methacrylate monomer, inorganic fillers (silica: particle diameter &lt;50μm), pigments, etc.</td>
<td>Approximately 38 vol%</td>
<td></td>
</tr>
<tr>
<td>Repair Primer Liquid</td>
<td>ethanol, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repair Liquid Liquid</td>
<td>methacrylate monomer, etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Items marked “Flow” have low viscosity, and are referred to as “Body Resin Flow” or “TWiNY Flow”.

**[Intended use and effect / efficacy]**

This product is intended to be used for dental crown restoration or recontouring by means of facing crowns, jacket crowns, bridges, inlays, onlays, and veneers, and for fabricating temporary crowns or repairing artificial crowns outside the mouth.

**[Product Specification]**

Test Method: ISO 10477

<table>
<thead>
<tr>
<th>Items</th>
<th>Requirement (Type 2 · Class 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth of Cure (Hardness)</td>
<td>Top surface: ≤ 18Hv0.5</td>
</tr>
<tr>
<td></td>
<td>Bottom surface: not more than 70% of the top surface</td>
</tr>
<tr>
<td>Flexural Strength</td>
<td>≥ 80 MPa</td>
</tr>
<tr>
<td>Water Sorption</td>
<td>≤ 40 µg/gm</td>
</tr>
<tr>
<td>Solubility</td>
<td>≤ 7.5 µg/gm</td>
</tr>
</tbody>
</table>

**[Instructs]**

Curing procedure is given in the table.

<table>
<thead>
<tr>
<th>Items</th>
<th>LED CUBE Master*</th>
<th>Other light curing machine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luna Wing Primer Paste/Invisible-Opaque</td>
<td>About 10 sec.</td>
<td>About 90 sec.</td>
</tr>
<tr>
<td>Opaque</td>
<td>About 30 sec.</td>
<td>About 180 sec.</td>
</tr>
<tr>
<td>Body Resin</td>
<td>About 10 sec.</td>
<td>About 60 sec.</td>
</tr>
<tr>
<td>Final Light Curing</td>
<td>About 90 sec.</td>
<td>About 180 sec.</td>
</tr>
<tr>
<td>Heat Curing</td>
<td>About 110°C for about 15 min.</td>
<td></td>
</tr>
</tbody>
</table>

* LED light curing machine from Yamakin

Prior to use, carefully read the instructions manual.

**[Jacket Crowns]**

1. **Making Plaster Model and Resin Spacer Application**
   - Make a plaster model in accordance with normal practice.
   - Apply Resin Spacer on surface, except margin area and dry. Then for easier removal of jacket mould, apply Repair Liquid thinly on margin area and dry.
   - Apply Resin Spacer thinly with a flat brush and light cure for about 180 sec. In cases where the metal color is visible, repeat this step until the metal color is concealed. Do not apply thickly at one time.
   - **Application of Body Resin and TWiNY Flow and Light Curing**
     - Apply Cervical or Opaque Dentine starting from the neck to the incisal area, applying progressively thinner, taking subsequent color gradation into consideration. Light cure for about 60 sec. Then, apply Dentine to form the required dentine core shape and light cure for about 60 sec. Using TWiNY Flow makes it easier to layer cervical area and cavity bottom.
     - **Application of Enamel and Translucent and Light Curing**
       - Apply Enamel to form the required crown shape and light cure for about 60 sec. In cases where Translucent is required, apply Translucent and light cure for about 60 sec.
       - Use TWiNY Flow can avoid entrapping of air and makes it easier to create delicate color tones and shaping.
     - **Final Light Curing**
       - After final layering, apply Resin Air Barrier as thinly as possible to avoid immature curing and leave it for about 60 sec to dry. Then light cure it for about 180 sec as a final light curing. If Resin Air Barrier is applied thickly, it is difficult to dry. The brush used to apply Resin Air Barrier should be washed with water after use.

2. **Correction to Shape**
   - **Shapes**
   - Correct the shape using a carborundum or diamond point.
     - **Additional Layering:** In cases where additional layering after correcting the shape is needed, apply Repair Primer thinly with a brush on or around corrected surface and leave it for about 60 sec to dry. Apply Repair Primer thinly on the same area. Then, apply composite resin such as Dentine or Enamel correspondingly and light cure.
   - **Body Resin Flow**
     - Apply Air Barrier on the additional layering areas, then light cure for about 180 sec as a final curing. Again correct and adjust the shape to finish.
   - **Heat Curing**
     - Remove the jacket crown from the plaster model and heat cure it at about 110°C for about 15 minutes using a heat curing machine.
   - **Finishing**
     - Remove any scabs with paper cone and silicron point to make the surface smooth.
   - **Polishing and Complete**
     - Polish by using brush and fabric buff with polishing materials such as C&B Diamond polisher or C&B NANO Diamond Polisher to finish. Finally, sand-blast (about 0.1~0.25MPa) the inside of the jacket crown using alumina powder (about 50 ~ 100µ), then use a steam cleaner or an ultrasonic cleaner to wash, and then dry to completion.

3. **Inlays and Onlays**

   (1) **Making plaster model and Resin Spacer Application**
   - Make a plaster model in accordance with normal practice. Apply Resin Spacer inside of the cavity and dry. If there are undercuts in the cavity, block them out using Resin Spacer or wax in advance.
   - **Application of Body Resin and TWiNY Flow and Light Curing**
     - **Application of Dentine, Cervical Translucent (CT1,CT2,CT4) and Light Curing**
       - Apply Dentine or Cervical Translucent from the cavity bottom and light cure for about 60sec. Using Body Resin Flow makes it easier to layer cervical area and cavity bottom. In case the abutment color is required to be concealed, or light goes through unnecessarily, apply Opaque or Opaque Dentine at the bottom of the cavity.
       - **Enamel Application and Light Curing**
         - Apply Enamel to the bottom of the cavity and light cure for about 60 sec.
         - Using TWiNY Flow can avoid entrapping of air and makes it easier to create delicate color tones and shaping.
       - **Final Light Curing**
         - After final layering, apply Resin Air Barrier as thinly as possible to avoid immature curing and leave it for about 60 sec to dry. Then light cure it for about 180 sec as a final light curing. If Resin Air Barrier is applied thickly, it is difficult to dry. The brush used for Air Barrier should be washed with water after use.
     - **Corrections to Shape**
       - **Correct the shape using a carborundum or diamond point.**
         - **Additional Layering:** In cases where additional layering after correcting the shape is needed, apply Repair Primer thinly with a brush on or around corrected surface and leave it for about 60 sec to dry. Apply Repair Liquid thinly on the same area. Then, apply composite resin such as Dentine or Enamel correspondingly and light cure.
       - **Apply Resin Air Barrier on the additional layering areas, then light cure for about 180 sec as a final curing. Again correct and adjust the shape to finish.**
       - **Heat Curing**
         - Remove the inlays and onlays from the plaster model and heat cure them at about 110°C for about 15 minutes using a heat curing machine.
       - **Finishing**
         - Remove any scabs with paper cone and silicron point to make the surface smooth.
       - **Polishing and Complete**
         - Polish by using brush and fabric buff with polishing materials such as C&B Diamond polisher or C&B NANO Diamond Polisher to finish. Finally, sand-blast (about 0.1~0.25MPa) the inside of the inlay or onlay using alumina powder (about 50 µm), then use a steam cleaner or an ultrasonic cleaner to wash, and then dry to completion.

4. **Facing Crowns and Bridges and Gum**

   (1) **Making Metal Framework**
   - Make a plaster model in accordance with normal practice. Cut back and make the crown shape using wax; then apply bonding material and retention beads on facing part to make wax pattern (mould of metal frame). Then cast the metal following its manufacturer’s instruction.
   - **Alumina Treatment of Metal Framework**
     - **Translucent** (about 0.2~0.25MPa) the surface with alumina powder (about 50 ~ 100µ); then use steam cleaner or an ultrasonic cleaner to wash, then dry.
Technical Directions and Points for Attention

1. For light-curing this product, use a halogen lamp, xenon lamp or LED with an effective wavelength of 400-500 nm. In cases where other medical curing equipment is to be used, or if you have any questions about curing machines, please feel free to contact us. For heat-curing, use a dental heat-curing machine which can be set at 110°C for 1.5 min.

2. In clinical cases with a high risk of fracture such as malocclusion or bruxism, the occlusal area of the opposing tooth must be metal-coated in order to avoid fractures.

3. Close the cap promptly and tightly after using this product.

4. Use separate brushes for Primer Paste, Opaque, TWiNY Flow and Light Curing. Do not use Base on facing crowns and bridges since there is difficulty to dry. The brush used for Repair Air Barrier should be washed with water after use.

5. Connections to Shape

   a. Correct the shape using a carborundum or diamond point.

   b. Additional layering: In cases where additional layering after correcting the shape is needed, apply Repair Primer thinly with a brush on a ground coated surface and leave it for about 60 sec. to dry. Apply Repair Liquid thinly on the same area. Then, apply composite resin such as Dentine or Enamel correspondingly and light cure. With Primer Paste, Opaque Resin, and Custom Color, apply Primer Paste thinly with a brush on the additional area, then light cure for about 180 sec. as a final curing. Again correct and adjust the shape to finish.

6. Heating Cure

   a. Remove any excess with paper cone and silicone to make the surface smooth.

   b. Polish and Complete

   i. Polish by using brush and fabric with polishing material such as C&B Diamond Polisher or C&B NANO Diamond Polisher to finish.

   ii. Finishing

   a. Remove any excess with paper cone and silicone to make the surface smooth.

   b. Polish and Complete

   i. Polish by using brush and fabric with polishing material such as C&B Diamond Polisher or C&B NANO Diamond Polisher to finish.

   ii. Finishing

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