Identification Number: 222AABZX00121000

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>Items</th>
<th>State</th>
<th>Components</th>
<th>Inorganic Filler Content Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opaque Resin</td>
<td>Paste</td>
<td>methacrylate monomer, inorganic fillers (silica: particle diameter &lt;50µm), pigments, etc.</td>
<td>Approximately 37 vol%</td>
</tr>
<tr>
<td>Body Resin</td>
<td>Paste</td>
<td>methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: particle diameter &lt;20µm), pigments, etc.</td>
<td>Approximately 56 vol%</td>
</tr>
<tr>
<td>Body Resin Flow</td>
<td>Paste</td>
<td>methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: particle diameter &lt;15µm), pigments, etc.</td>
<td>Approximately 48 vol%</td>
</tr>
<tr>
<td>Stain</td>
<td>Paste</td>
<td>methacrylate monomer, inorganic fillers (silica: particle diameter &lt;50µm), pigments, etc.</td>
<td>Approximately 58 vol%</td>
</tr>
<tr>
<td>Repair Primer</td>
<td>Liquid</td>
<td>ethanols, etc.</td>
<td>–</td>
</tr>
<tr>
<td>Repair Liquid</td>
<td>Liquid</td>
<td>methacrylate monomer, etc</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 ]
To be used for 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 Bottom surface: not less 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/mm²</td>
</tr>
<tr>
<td>Solubility</td>
<td>≤ 7.5 µg/mm²</td>
</tr>
</tbody>
</table>

[ Instructions ]
Curing procedure is as given in the table.

<table>
<thead>
<tr>
<th>Items</th>
<th>LED CURE Master*</th>
<th>Other light curing machine</th>
</tr>
</thead>
<tbody>
<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

[ 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 Resin Separator thinly on margin area and dry.

(2) Opaque Application and Light Curing
Apply Opaque 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 thinly at one time.

(3) Application of Body Resin and TWiNY Flow and Light Curing
1. Application of Cervical, Opaque Dentine and Dentine and Light Curing
Apply Opaque 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.
2. 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.

Using TWiNY Flow can avoid entrapment of air and makes it easier to create delicate color tones and shapings.

(4) 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.

(5) 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 0.1~0.2µm) the inside of the jacket crown using alumina powder (about 50 µm) then use a steam cleaner or an ultrasonic cleaner to wash, and then dry to completion.

[ Inlays and Onlays ]
(1) Making plaster model and Resin Spacer Application
Make a plaster model in accordance with normal practice. Apply Resin Separator inside of the cavity and dry. If there are under-cut spaces in the cavity, block them out using Resin Spacer or Wax in advance.

(2) Application of Body Resin and TWiNY Flow and Light Curing
1. Application of Dentine, Cervical Translucent (CT1,CT2,CT3,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 outside the mouth.

(3) 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 grained 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 Air Barrier on the additional layering area, then light cure for about 180 sec as a final curing. Again correct and adjust the shape to finish.

(4) 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.

(5) 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 0.1~0.2µm) the inside of the jacket crown using alumina powder (about 50 µm) then use a steam cleaner or an ultrasonic cleaner to wash, and then dry to completion.

[ 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.

(2) Alumina Treatment of Metal Framework
Sand-blast (about 0.2~0.25µm) the surface with alumina powder (about 50 µm) then use steam cleaner or ultrasonic cleaner to wash, then dry.

Prior to use, carefully read the instructions manual.
Precautions

- Apply Luna Wing Primer Paste thinly and evenly with a flat brush. Leave it for about 120 sec., to enhance bonding strength.
- Do not apply thickly at one time.
- Do not operate the syringe at low temperature as it may break. Please use this product at an ambient temperature of 20-25℃.
- Do not use the syringe at low temperature as it may break.
- The expiry date printed on the package is based on our authentication.
- The expiry date printed on the package refers to use expiry date.
- Twin NY flow has larger polymerization shrinkage than TWiNY body resin. When in use on a pallet or mixing paper, this product should be protected by a shade cover.
- Do not mix body resin with other materials, and do not mix more than one type of body resin to prevent air bubble entrapping and deterioration in quality of material properties.
- It is technically O.K. to mix more than two different TWiNY Flow products, but do not mix TWiNY Flow and TWiNY body resin.
- When using on a pallet or mixing paper, this product should be protected by a shade cover.
- Do not use Base on facing part, as it is designed only for the pontic area.

[Precautions]

- Provide adequate ventilation (several times per hour) during operation.
- When cutting and polishing, use exhaust fan and dust-tight mask as approved by your local public safety agency in order to avoid inhaling dust. Wear safety goggles to protect the eyes.
- Do not use the syringe at low temperature as it may break.
- Only adequately certified personnel should handle this product.
- Do not use the syringe at low temperature as it may break.
- Please use this product at an ambient temperature of 20-25℃ as the optimal temperature for easy handling.
- In cases where the product has been stored at 4℃, leave it at room temperature for about 20℃ for more than 20 min. in order to prepare product for further use.
- In cases where Resin Air Barrier has been stored at a low temperature for a long time, its viscosity will become higher. In such cases, close the cap tightly and put the product in hot water for about 5 min. so that viscosity will return to normal.

[Important Basic Caution]

- Do not use this product if you have any signs of allergy, such as irritation or rash, appears in patients. If symptoms persist, seek medical attention.
- Use Gum Stain to characterize blood vessels or discolored gum. Gum Stain cannot be used for surface layer, but is to be used between layers.
- Gum Stain cannot be used for surface layer, but is to be used between layers.
- Do not 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. for intermediate translucency expressions between Translucent and Enamel, use Trans Enamel. For discolored expressions, use Effect items partially. Using TWiNY Flow can avoid entrapping of air and makes it easier to create delicate color tones and shading.

[Technical Directions and Points for Attention]

- For light-curing this product, use a halogen lamp, xenon lamp, or LED with an effective wavelength of 400-500 nm.
- Please feel free to contact us for further assistance. Contact us for further assistance. Use a dental heat curing machine which can be set at 110℃ for 15 min.
- Please note that TWiNY Flow has larger polymerization shrinkage than TWiNY body resin.
- Do not push too hard when using a metallic instrument. It may cause the resin to darken, since the inorganic fillers in TWiNY will scratch against the surface of the metal instrument. Plastic instruments or instruments coated with hard materials such as titanium nitride are recommended for TWiNY application.
- Use the syringe at low temperature as it may break.
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