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Controlled Medical Device - Composite Resin for Crowns and Bridges

Luna-Wing

[Product description]

[Intended purpose]

This material is a hard resin for dental crowns suitable for occlusal surfaces, and is used for fabrication of crown restorations such as anterior crowns, jacket crowns and bridges, or temporary crowns, or for the repair of artificial crowns inside or outside the mouth.

[Indications]

- Restoration of crowns by means of anterior crowns, jacket crowns, and bridges
- Fabrication of temporary crowns, etc.
- Repair of artificial crowns inside and outside the mouth

[Intended users]

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]

As a hard resin and an adhesive material for crowns, a tooth of a patient is restored by applying it to a surface or an inside of a dental restoration.

[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.

Item/Composition	State	Ingredients	Inorganic Filler Content Rate
Opaque Resin	Paste	methacrylate monomer, inorganic fillers(silica: particle diameter <50 μ m), pigments, etc.	Approximately 37 vol%
Body Resin Body Resin Flow	Paste	methacrylate monomer, organic fillers, inorganic fillers(silica: particle diameter <0.5 μ m), pigments, etc.	Approximately 44 vol%
Stain	Paste/Liquid	methacrylate monomer, inorganic fillers(silica: particle diameter <50 μ m), pigments, etc.	Approximately 38 vol%
Primer Paste	Paste	methacrylate monomer, inorganic fillers(silica: particle diameter<50 μ m), silane coupling agent, pigments, etc	Approximately 37 vol%

*Items marked "Flow" have low viscosity, and are referred to as "Body Resin Flow" and in contrast, conventional types are referred to as "Body Resin".

Principles: This material is cured by visible light.

[Intended use and effect / efficacy]

This product is intended to use for dental crown restoration such as facing crowns, jacket crowns, and bridges and fabricating temporary crowns or repairing artificial crowns outside mouth.

[Product Specification]

Test method: ISO 10477

Items	Requirement (Type 2 - Class 2)
Depth of Cure (Hardness)	Top surface: \geq 18HV0.5 Bottom surface: not less than 70% of the top surface
Flexural Strength	\geq 80 MPa
Water Sorption	\leq 40 μ g/mm ³
Solubility	\leq 7.5 μ g/mm ³

[Instructions]

Curing procedure is as given in the table.

Also, 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.

Please contact your dealer for more information on effective wavelengths and light levels for polymerization devices.

Items	LED CURE Master*	Other light curing machine
Primer Paste Invisible Opaque	About 10 sec.	About 90 sec.
Opaque	About 30 sec.	About 180 sec.
※ Body Resin	Base	About 90 sec.
	Others	About 10 sec.
Body Resin Flow	About 10 sec.	About 60 sec.
Stain	About 10 sec.	About 60 sec.
Final Light Curing	About 90 sec.	About 180 sec.

※Body Resin (Cervical, Opaque Dentine, Dentine, Enamel, Translucent Enamel, Translucent, Effect and Base)

*LED light curing machine from YAMAKIN

[Facing Crown and Bridge]

(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 framework).

Then cast the metal following product instruction. In cases where this product is used for anterior tooth and facing crown, the occlusal area of the opposing tooth must be metal-coated to avoid fracture.

(2) Alumina Treatment of Metal Frame

Sand-blast (about 0.2~0.25MPa) the surface with alumina powder (about 50 μ m); then use a steam cleaner or an ultrasonic cleaner to wash, then dry.

(3) Primer Paste and Invisible Opaque Application and Light Curing

Apply Primer Paste evenly with a flat brush. Leave it for about 120 sec., to enhance bonding strength and light cure. Then apply Invisible Opaque with a flat brush to flow into the undercut area of retention beads and light cure. Apply thinly in margin area with no beads. Primer paste is a bonding material, but at the same time it can be used as Invisible Opaque, the use of Invisible Opaque is not necessary. In this case, Primer Paste should be applied to cover the undercut area of retention beads.

※Primer Paste cannot be used for gold alloys.

(4) Opaque Application and Light Curing

Apply opaque thinly 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.

Use Special Opaque Color to express transparency of the incisal area or to emphasize color of the neck.

(5) Base Application and Light Curing

For pontic part, apply Invisible Opaque to pontic area and light cure for about 90 sec. then apply Base.

(6) Application of Body Resin and Body Resin Flow and Light Curing

①Application of Cervical, Opaque Dentine and Dentine 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. If partial characterization or color adjustment is necessary, apply desired color with a round brush and light cure for about 60 sec. Using Body Resin Flow makes it easier to layer cervical area and white band of facing crown.

②Application 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. After final layering, light cure for about 180 sec. as a final light curing. Using Body Resin Flow can avoid entrapping of air and makes it easier to create delicate color tones and shaping.

(7) 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 bonding agent for additional layering such as Multi Primer REPAIR LIQUID ONE, etc. thinly, then apply body resin correspondingly. Then light cure for about 60 sec.

(8) Finishing

Remove any scars with paper cone and silicon point to make the surface smooth.

(9) Polishing

Polish using a brush and fabric buff with polishing material to finish.

[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 crown 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 thickly at one time.

(3) Application of Body Resin and Body Resin Flow and Light Curing

①Application of Cervical, Opaque Dentine and Dentine 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. If partial characterization or color adjustment is necessary, apply desired Stain color with a round brush and light cure for about 60 sec. Using Body Resin Flow makes it easier to layer cervical area.

②Application 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. After final layering, light cure for about 180 sec. as a final light curing. Using Body Resin Flow can avoid entrapping of air and makes it easier to create delicate color tones and shaping.

(4) 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 bonding agent for additional layering such as Multi Primer REPAIR LIQUID ONE, etc. thinly, then apply body resin correspondingly. Then light cure for about 60 sec.

(5) Finishing

Remove any scars with paper cone and silicon point to make the surface smooth

(6) Polishing

Polish by using a brush and fabric buff with polishing material to finish. Finally, sandblast (about 0.1~0.2MPa) the inside of the jacket crown using alumina powder (about 50 μ m), then use steam cleaner or ultrasonic cleaner to wash, and then dry.

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

- For light-curing this product, use a halogen lamp, xenon lamp, metal halide 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.
- As fractures may happen, this product cannot be used for molars and second premolars.
- In cases with a high risk of fracture such as malocclusion or bruxism, the occlusal contact area should be metal surface to avoid fracture of the prosthesis.
- Close the cap promptly and tightly after using this product.
- Use separate brushes for Primer Paste, Opaque, Stain and bonding agent for additional layering.
- When this material is in use on a pallet or mixing paper, it 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. (unproblematic) to mix more than two different Body Resin Flow products, but do not mix Body Resin and Body Resin Flow.
- Body Resin Flow is subject to air bubble formation during mixing. Please mix carefully.
- Stain must be applied on internal layer; please use Enamel or other products after Stain application.
- Avoid exposures to strong light or sunlight (near windows or laboratory lights, etc.) in order to prevent hardening of paste.
- Do not use Base on facing part, as Base is designed only for the pontic area.
- Please note that Body Resin Flow has larger polymerization shrinkage than Body Resin.
- As Body Resin Flow has the property of thixotropy*, the material near the tip of the nozzle can harden and become difficult to push out later. Please pull the piston back about 2mm when storing after use.

[Precautions]

- Provide adequate ventilation (several times per hour) during operation.
- When cutting and polishing cured product, use exhaust fan and anti-dust 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 this product outside the scope of recommended indications, effects or potency.
- Do not use this product in combination with other products.
- Only adequately certified personnel should handle this product.
- Do not operate the syringe at low temperature as it may break. Please use this product at an ambient temperature of 20-25°C is the optimal and recommended temperature for easy handling. In cases where the product has been stored at 4°C, leave it at a room temperature of around 20°C for more than 20 min. in order to prepare product for use.
- Dispose of this product as a medical waste to prevent infection.

[Important Basic Cautions]

[Important Basic Cautions]

- Stop using this product immediately if any signs of allergy, such as irritation or rash, appears in patients. If symptoms persist, seek medical advice.
- Operators must discontinue use if any signs of irritation or rash appear. If symptoms persist, seek medical attention.
- Do not handle uncured material of this product with bare hands. Wear plastic gloves and safety goggles to protect from irritation. Avoid direct skin and eye contact. In case of skin contact, wipe with alcohol cotton swab, and flush with plenty of running water. In case of

eye contact, immediately flush with plenty of running water, and consult a physician.

[Other Cautions]

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

[Handling and Storage]

- This product must be stored in out of contact with direct light sources at a temperature of 4-25°C.
- Do not store too many products in the same storage area.
- Equip with a fire extinguisher in work or storage area.
- 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]

- This product must be used before the expiry date printed on the package.
 - The expiry date printed on the package is based on our authentication.
 - The expiry date printed on the package refers to use expiry date.
- *(ex.: YYYY-MM means the last day of YYYY 'year'/MM 'month' as the expiry date)

[Package]

○ Opaque Resin

- Invisible Opaque (2.3ml): IvO
- Opaque (2.3ml): OA0, OA1, OA2, OA3, OA3.5, OA4, OB1, OB2, OB3, OB4, OC1, OC2, OC3, OC4, OD2, OD3, OD4
- Special Opaque Color (2.3ml): Ino1, Ino2, PO, MO

○ Body Resin

- Cervical 5g (3ml): CA1, CA2, CB1, CB2, CC1, CC2, CD1, CD2
- Dentine 5g (3ml): DA0, DA1, DA2, DA3, DA3.5, DA4, DB1, DB2, DB3, DB4, DC1, DC2, DC3, DC4, DD2, DD3, DD4
- Dentine (Harmonized Shade) 5g(3ml): DA2 HS, DA3 HS, DA3.5 HS
- Opaque Dentine 5g (3ml): ODA0, ODA1, ODA2, ODA3, ODA3.5, ODA4
- Opaque Dentine (Harmonized Shade) 5g(3ml): ODA2 HS, ODA3 HS, ODA3.5 HS
- Enamel 5g (3ml): E0, E1, E2, E3, E4, E0 Hard, E1 Hard, E2 Hard, E3 Hard, E4 Hard
- Enamel (Harmonized Shade) 5g(3ml): E2 HS, E3 HS, E2 HS Hard, E3 HS Hard
- Trans Enamel 5g (3ml): TE, TE Hard
- Translucent 5g (3ml): HVT, T, LVT, CT, HVT Hard, T Hard, LVT Hard, CT Hard
- Effect 5g (3ml): HV WE, WE, AM, OC, Coffee, Orange, L Gum, Gum, D Gum
- Base 5g (3ml): Base

○ Stain

- Stain (1ml): White, Milky, Pink, Salmon Pink, White Violet, Violet, Orange, Dark Orange, Red, Yellow, Blue, Brown, Red Brown, Dark Brown, A Shift, B Shift, C Shift, D Shift, Gray, Black
- Stain Clear (6ml): Clear
- Primer Paste (2.3 ml)

○ Body Resin Flow

- Cervical 3.8g (2.3ml): CA1 Flow, CA2 Flow
- Dentine 3.8g (2.3ml): DA2 Flow, DA3 Flow, DA3.5 Flow
- Dentine (Harmonized Shade) 3.8g (2.3ml): DA2 HS Flow, DA3 HS Flow, DA3.5 HS Flow
- Opaque Dentine 3.8g (2.3ml): ODA3 Flow
- Enamel 3.8g (2.3ml): E2 Flow, E3 Flow
- Trans Enamel 3.8g (2.3ml): TE Flow
- Translucent 3.8g (2.3ml): T Flow
- Effect 3.8g (2.3ml): WE Flow, Orange Flow, Gum Flow

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