英語版

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Controlled Medical Device - Composite Resin for Crowns and Bridges

TWiNY

[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	State	Components	Inorganic Filler Content Rate
Opaque Resin	Paste	methacrylate monomer, inorganic fillers (silica: particle diameter <50μm), pigments, etc.	Approximately 37 vol%
Body Resin	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: particle diameter <20μm), pigments, etc.	Approximately 56 vol%
Body Resin Flow	Paste	methacrylate monomer, inorganic fillers (silica, alumina, and zirconia: particle diameter <15μm), pigments, etc.	Approximately 48 vol%
Stain	Paste	methacrylate monomer, inorganic fillers (silica: particle diameter <50μm), pigments, etc.	Approximately 38 vol%
Repair Primer	Liquid	ethanol,etc.	—
Repair Liquid	Liquid	methacrylate monomer, etc	—

・Items marked "Flow" have low viscosity, and are referred to as "Body Resin Flow" or "TWiNY Flow". In contrast, conventional types are referred to as "Body Resin".

Principles: This material is cured by visible light and heat.

[Intended use and effect / efficacy]

This product is intended to be used for dental crown restoration or re-contouring by means such as 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

Items	Requirement (Type 2 - Class 2)
Depth of Cure (Hardness)	Top surface: ≧ 18HV0.5 Bottom surface: not less than 70% of the top surface
Flexural Strength	≧ 80 MPa
Water Sorption	≦ 40 μg/mm³
Solubility	≦ 7.5 μg/mm³

[Instructions]

Curing procedure is as given in the table.

Items	LED CURE Master*	Other light curing machine
(Luna-Wing) Primer Paste/Invisible Opaque	About 10 sec.	About 90 sec.
Opaque	About 30 sec.	About 180 sec.
Body Resin	About 10 sec.	About 60 sec.
Body Resin Flow	About 10 sec.	About 60 sec.
Final Light Curing	About 90 sec.	About 180 sec.
Heat Curing	About 110℃ for About 15 min.	

* 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 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 TWiNY 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. Using TWiNY Flow makes it easier to layer cervical area and cavity bottom.
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.
Using TWiNY Flow can avoid entrapping of air and makes it easier to create delicate color tones and shaping.
③Final 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.

(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 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.

(5) Heat Curing
Remove the jacket crown from the plaster model and heat cure it at about 110℃ for about 15 minutes using a heat curing machine.

(6) Finishing
Remove any scars with paper cone and silicon point to make the surface smooth.

(7) 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 0.1～0.2MPa) the inside of the jacket crown using alumina powder (about 50μm), 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
①Application 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 unnecessarily, apply Opaque or Opaque Dentine at the bottom of the cavity.
②Enamel Application and Light Curing
Apply Enamel to form the required crown shape 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.
③Final 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.

(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 Resin 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 inlays and onlays from the plaster model and heat cure them at about 110℃ for about 15 minutes using a heat curing machine.

Prior to use, carefully read the instructions manual.

(5) Finishing
Remove any scars with paper cone and silicon point to make the surface smooth.
(6) 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 0.1～0.2MPa) the inside of the inlay or onlay using alumina powder (about 50μm), 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 0.2～0.25MPa) the surface with alumina powder (about 50μm); then use steam cleaner or ultrasonic cleaner to wash, then dry.
(3) Luna Wing Primer Paste and Invisible Opaque Application and Light Curing
Apply Luna Wing Primer Paste thinly and evenly with a flat brush. Leave it for about 120 sec., to enhance bonding strength. Light cure for about 90 sec. Then apply Invisible Opaque to flow into the undercut area of retention beads. Apply thinly in margin area with no beads. Light cure about 90 sec. 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 thickly enough to flow into 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.
For pontic part, apply Invisible Opaque to pontic area and light cure for about 90 sec. then apply base and light cure for about 180 sec. Use Special Opaque Color to express transparency of the incisal area or to emphasize colors of the neck. Use Gum Opaque to conceal the metal color and light cure for about 180 sec. 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.
(5) 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. Using TWiNY 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.
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 shaping.
③Gum Application and Light Curing
Apply Gum and light cure for 60 sec. to reproduce gingival area. In order to express Melanin pigment or transparency of surface layer, apply Gum Modifier and light cure for about 60 sec. Using Body Resin Flow makes it easier to create delicate color tones.
※In cases where Gum is used for a wide range of connected teeth, application should be carried out one by one individually to avoid deformation of the metal frame caused by curing shrinkage.
④Final 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 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 Resin Air Barrier should be washed with water after use.
(6) 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 Resin 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.
(7) Heat Curing
Remove facing crowns and bridges from the plaster model and heat cure it at about 110℃ for about 15 min. using a heat curing machine.
(8) Finishing
Remove any scars with paper cone and silicon point to make the surface smooth.
(9) Polishing and Complete
Polish by using brush and fabric buff with polishing material such as C&B Diamond Polisher or C&B NANO Diamond Polisher to finish.

[N.B.: Technical Directions and Points for Attention]
1. 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. For heat curing, use a dental heat curing machine which can be set at 110℃ for 15 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, Stain, Repair Primer, Repair Liquid and Resin Air Barrier.
5. If Repair Primer or Repair Liquid is applied by dripping it directly onto metal frames, there may be deterioration in adhesive strength if applied in excess quantity. When applying Repair Primer or Repair Liquid to a metal frame, apply using a fine brush, and as much as possible apply in a single fine layer.
6. When applying 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 scrape against the surface of the metal instrument. Plastic instruments or instruments coated with hard materials such as titanium nitride are recommended for TWiNY application.
7. When in use on a pallet or mixing paper, this product should be protected by a shade cover.
8. 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.
9. It is technically O.K.(unproblematic) to mix more than two different TWiNY Flow products, but do not mix TWiNY Flow and TWiNY body resin.
10. TWiNY Flow is subject to air bubble formation during mixing. Please mix carefully.
11. Please note that TWiNY Flow has larger polymerization shrinkage than TWiNY body resin.
12. As TWiNY 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 2 mm when storing after use.
13. Stain must be applied on internal layer; please use Enamel or other products after Stain application.
14. Avoid exposures to strong light or sunlight (near windows or laboratory lights, etc.) in order to prevent hardening of paste.
15. Do not use Base on facing part, as it is designed only for the pontic area.

[Precautions]
① Provide adequate ventilation (several times per hour) during operation.
② 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.
③ Do not use this product outside the scope of recommended indications, effects or potency.
④ Do not use this product in combination with other products.
⑤ Only adequately certified personnel should handle this product.
⑥ Do not operate the syringe at low temperature as it may break. Please use this product at an ambient temperature of 20-25℃ is the optimal temperature for easy handling. In cases where the products has been stored at 4℃, leave it at a room temperature of around 20℃ for more than 20 min. in order to prepare product for use.
⑦ In cases where Resin Air barrier has been stored at a low temperature over 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.
⑧ 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 rush, appears in patients. If symptoms persist, seek medical attention.
② Operators must discontinue use if any signs of irritation or rash appear. If symptoms persist, seek medical attention.
③ Do not touch 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]
① This product must be stored in out of contact with direct light sources at a temperature of 4-25℃.
② Do not store too many products in the same storage area.
③ Equip with a fire extinguisher in work or storage area.
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.
*(ex.; YYYY-MM means the last day of YYYY 'year'/MM 'month' as the expiry date)

[Package]
① Opaque Resin
・Invisible Opaque 2.0ml: IvO
・Opaque 2.0ml: OA1, OA2, OA3, OA3.5, OA4, OB1,OB2,OB3,OB4,OC1,OC2,OC3,OC4,OD2,OD3,OD4
・Opaque (Red Plus Shade) 2.0ml: OA2 R, OA3 R, OA3.5 R
・Opaque (Whitening Shade) 2.0ml: OW1, OW2, OW3
・Opaque (Gum Shade) 2.0ml: OG1, OG2, OG3, OG4, OG5, OG Or
・Special Opaque Color 2.0ml: InO1, InO2, MO
② Body Resin and Body Resin Flow
・Cervical 4.8g (2.6ml): CA1, CA2, CB1, CB2, CC1, CC2, CD1, CD2
3.5g (2.0ml): CA1 Flow, CA2 Flow
・Cervical (Red Plus Shade) 4.8g (2.6ml): CA1 R, CA2 R
・Opaque Dentine4.8g (2.6ml): ODA1, ODA2, ODA3, ODA3.5, ODA4, ODB1, ODB2, ODB3, ODB4, ODC1, ODC2, ODC3, ODC4, ODD2, ODD3, ODD4
・Opaque Dentine (Red Plus Shade) 4.8g (2.6ml): ODA2 R, ODA3 R, ODA3.5 R
・Dentine 4.8g (2.6ml): DA1, DA2, DA3, DA3.5, DA4, DB1, DB2, DB3, DB4, DC1, DC2, DC3, DC4, DD2, DD3, DD4
3.5g (2.0ml): DA1 Flow, DA2 Flow, DA3 Flow, DA3.5 Flow, DA4 Flow, DB1 Flow
・Dentine (Red Plus Shade) 4.8g (2.6ml): DA2 R, DA3 R, DA3.5 R
・Dentine (Whitening Shade) 4.8g (2.6ml): DW0, DW1, DW2, DW3
・Gum (Gum Shade) 4.8g (2.6ml): G1, G2, G3, G4, G5, G6, G7, G Or
3.5g (2.0ml): G1 Flow, G3 Flow, G5 Flow, G7 Flow, G Or Flow
・Gum (Gum Modifier) 4.8g (2.6ml): GM Gray, GF Trans
3.5g (2.0ml): GM Gray Flow, GM Trans Flow
・Enamel 4.8g (2.6ml): E0, E1, E2, E3, E4, E1 Clear, E2 Clear, E3 Clear, E4 Clear, E5 Clear
3.5g (2.0ml): E1 Flow, E2 Flow, E3 Flow
・Trans Enamel 4.8g (2.6ml): TE
3.5g (2.0ml): TE Flow
・Translucent 4.8g (2.6ml): HVT, T, LVT, CT1, CT2, CT3, CT4, T Glass, T Blue, T Glass Clear
3.5g (2.0ml): HVT Flow, T Flow, LVT Flow, CT2 Flow, CT4 Flow, T Glass Flow, T Blue Flow, T Glass Clear Flow
・Effect 4.8g (2.6ml): HV WE, WE, AM, OC, Coffee, Orange,
3.5g (2.0ml): WE Flow, AM Flow, OC Flow, Coffee Flow, Orange Flow
・Base 4.8g (2.6ml): Base
③ Stain
・Stain 1ml: G Dark Red, G Red, G Milky, G Violet
④ Repair Liquid 6ml
⑤ Repair Primer 7ml

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