

Identification Number: 226AABZX00069000

Controlled Medical Device –
Bonding Material for Dental Metal
Bonding Material for Dental Ceramics
Bonding Material for Dental Resin

Multi Primer

[Product description]**[Intended purpose]**

Adhesion of resin-based materials to any dental metal restorations or devices, dental ceramic restorations or devices, or resin-based restorations improves the workability of resin construction.

[Indications]

Multi Primer is suitable for use with dental metal restoration materials and devices, or for use with dental zirconia restoration materials and devices, or for use with dental resin restoration materials and devices. In particular, Multi Primer PASTE is suitable for use with metals. Multi Primer LIQUID is suitable for use with metals and zirconia. Multi Primer REPAIR LIQUID ONE is available for work with resins. Offering firm resin adhesion, Multi Primer enhances operability in resin application.

[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 an adhesive material, it is applied to the surface or interior of a dental restoration to restore the patient's teeth.

[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 Description]

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

| Item | State | Ingredients |
|--------------------------------|--------|---------------------------------------------------------|
| Multi Primer PASTE | Paste | methacrylate monomer, inorganic fillers, pigments, etc. |
| Multi Primer LIQUID | Liquid | ethanol, etc. |
| Multi Primer REPAIR LIQUID ONE | Liquid | methacrylate monomer, etc |

Description of these materials is as follows.

| Item | Description |
|--------------------------------|--------------------------------------------------------------|
| Multi Primer PASTE | This material is adhesive primer and cured by visible light. |
| Multi Primer LIQUID | This material is adhesive primer. |
| Multi Primer REPAIR LIQUID ONE | This material is adhesive primer and cured by visible light. |

[Intended use and effect / efficacy]

This product is intended to be used to bond indirect composite resin material to dental restorations and devices made of metal, zirconia, or resin. Do not use this product for other purposes.

Prior to use, carefully read the instructions manual.

[Product Specifications]

| Item | Testing Material | Specification | Test Method |
|--------------------------------|---------------------------------------------------------|-----------------|--------------------------------------------------|
| Multi Primer PASTE | Metal* ¹ | 30 MPa and | Compliant with ISO/TS11405 Tensile Bond Strength |
| Multi Primer LIQUID | Metal* ¹ | 30 MPa and | |
| | Zirconia* ¹ | 20 MPa and | |
| Multi Primer REPAIR LIQUID ONE | Indirect Composite Resin for Dental Crown* ¹ | 10 MPa and over | |
| | Dental Acrylic Resin* ² | 8 MPa and over | |

*1) Indirect composite resin for dental crown is used with the testing materials.

*2) Dental acrylic resin is used with a testing material.

[Instructions]

Curing procedure is as given in the table.

| Process | LED CURE Master* | Other curing machine |
|---------------------------------------|------------------|----------------------|
| Curing Multi Primer PASTE | About 10 sec. | About 90 sec. |
| Curing Multi Primer REPAIR LIQUID ONE | About 10 sec. | About 60 sec. |

*LED light curing machine from Yamakin

[Materials for use in combination with Multi Primer Series]

Indirect composite resin: Luna-Wing and TWiNY

[Instructions for Use]

· In case of Building-Up composite resin for crowns and bridges on a metal framework

- 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 its manufacturer's instruction.
- Alumina Treatment of Metal Framework
Sand-blast (about 0.2~0.25MPa) the surface with alumina powder (about 50 μm); then use steam cleaner or ultrasonic cleaner to wash, then dry.
- Multi Primer PASTE or LIQUID Application and Light Curing
 - Multi Primer PASTE Application
Apply Multi Primer PASTE to flow into the undercut area of retention beads. Leave it for about 120 sec., to enhance bonding strength. Light cure.
 - Multi Primer LIQUID Application
Apply Multi Primer LIQUID and leave it about for 60 sec. to dry.
- Resin Application
Follow instructions for indirect composite resin and build-up.
Since Multi Primer PASTE is the same shade as the Invisible Opaque shades of Luna-Wing and TWiNY, the layering step of Invisible Opaque and light curing are not necessary.

· In case of Building-Up composite resin for crowns and bridges on a zirconia framework

- Making Zirconia Framework
Shape a zirconia framework following manufacturer's instructions. Design the surface terraced and the level difference should be about 0.1mm.
- Alumina Treatment of Zirconia Framework
Sand-blast (about 0.2~0.25MPa) the surface with alumina powder (about 50 μm); then use steam cleaner or ultrasonic cleaner to wash, then dry.
- Multi Primer LIQUID Application
Immediately after washing and drying, apply Multi Primer LIQUID and leave it to dry for about 60 sec.
- Resin Application
Follow instructions for indirect composite resin and build-up.

• **Additional Layering on Resin Surface**

(1) Surface Treatment of Resin Surface

Grind resin surface with a carborundum or diamond point and make the surface rough. Use steam cleaner or ultrasonic cleaner to wash, and then dry.

(2) Application of Multi Primer REPAIR LIQUID ONE and Light Curing

Apply Multi Primer REPAIR LIQUID ONE and leave undisturbed for about 120 sec. Then, light cure.

(3) Resin Application

Follow instructions for indirect composite resin and build-up.

• **Repair of Fractured Resin Surface**

(1) Preparation of Fractured Surface

Grind fractured surface with a carborundum or diamond point and make the surface receptive for application. Use steam cleaner or ultrasonic cleaner to wash, and then dry.

(2) Application of Multi Primer REPAIR LIQUID ONE and Light Curing

Apply Multi Primer REPAIR LIQUID ONE and leave undisturbed for about 120 sec. Then, light cure.

(3) Resin Application

Follow instructions for indirect composite resin and build-up.

[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.
2. Close the cap promptly and tightly after using this product.
3. Use separate brushes for Multi Primer PASTE, Multi Primer LIQUID, and Multi Primer REPAIR LIQUID ONE.
4. Thoroughly check in advance all instructions and precautions for each medical device to be used in combination with this product.
5. Do not apply Multi Primer LIQUID onto a framework directly. Too much Primer might get poured onto the framework, making the bonding strength weaker. Apply primer onto a round thin brush and then apply it onto the framework as thinly as possible.
6. Apply Multi Primer LIQUID onto a zirconia framework immediately after it has been washed and dried. The bonding strength will be significantly weaker if the framework is left undisturbed after drying, for reasons such as impurities adhering to the surface of the framework, etc.
7. When this material is used on a pallet or mixing paper, it should be protected by a shade cover.
8. During application, avoid placing in areas with strong light, such as near windows, or directly under lighting. Doing so may cause curing of the material.
9. It is recommended to use this product for performing restoration outside the mouth.

[Precautions]

- ① Multi Primer LIQUID is flammable. Do not use this product in proximity to fire.
- ② Provide adequate ventilation (several times per hour) during operation.
- ③ 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.
- ④ Do not use this product outside the scope of recommended indications, effects or potency.
- ⑤ Do not mix this product in combination with other bonding products for metals, zirconia or resins. Doing so may impair the functionality of this product.
- ⑥ Only adequately certified personnel should handle this product.
*It is recommended to use this product at an ambient temperature of 20-25°C for easy handling.
- ⑦ 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 rash, 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.

[Handling and Storage]

- ① This product must be stored in out of contact with direct light sources at a temperature of 4-25°C
- 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 Multi Primer PASTE 2ml
- ② Multi Primer LIQUID 7ml
- ③ Multi Primer REPAIR LIQUID ONE 6ml

 YAMAKIN

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