

Controlled Medical Device –
Dental glazing material
Coloring material for polymer-based crown
Bonding Material for Dental Resin

Nu:le Coat

[Product description]

[Intended purpose]

Nu:le Coat is used to glaze or harden the surface of resin restorations, adjust the color of polymer-based crown restorations and bond resin restorations.

[Indications]

- Glazing or hardening the surface of dental restorations
- Characterization or color adjustment of polymer-based crown restorations
- Bonding of resin-based restorations built up on PEEK-based dental resin materials.

[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]

Repair a patient's teeth by applying to the surface or interior of a dental restoration as a dental adhesive filling material.

[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.

[Shape, Composition and Principles]

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

Constituent Name	State	Ingredients
Nu:le Coat Gel	Gel	Multifunction monomers, inorganic fillers, etc.
Nu:le Coat Liquid (Clear, A plus, B plus, C plus, D plus, White, Brown, Gray, Yellow, Orange, Blue, Red, Pink, Black, Gum, Dark Brown HV)	Liquid	Methacrylic acid monomers, multifunction monomers, inorganic fillers, colorants, etc.

[Principle]

This product is applied to the surface or inside of the dental restoration, and cured by irradiation with visible light.

[Intended Use and Effects/Efficacy]

- Glazing of the surface of dental restorations (composite resin for crown and bridges, acrylic resin, resin-based dental restorative material, etc.)
- Characterization and color adjustment of polymer-based crown restorations (composite resin for crown and bridges, resin material for dental milling and machining, resin-based dental restorative material, etc.)
- It is not intended to characterize natural teeth.
- Surface treatment when resin-based restorations (composite resin for crown and bridges, etc.) are applied on PAEK-based (PEEK, PEKK, etc.), polycarbonate resin material for dental milling and machining.

[Instructions for Use]

The conditions for the light curing device and curing time are shown in the following table.

Light curing process	LED Cure Master *1	Dental curing light*2
Pre-curing	30 sec.	10 sec.
Final curing	60 sec.	20 sec.

*1 Dental curing device sold by YAMAKIN.

*2 Dental curing device for practice: Please refer to the instructions of each device and confirm that the light irradiator to be used has an effective wavelength (Purple LED light, etc.: 400 ±20 nm) for this product. For the effective wavelength, contact the distributor of the light curing device.

[Materials for use in combination with this product]

Composite resin for crown and bridges: Luna-Wing, TWiNY, etc.

Resin material for dental milling and machining: KZR-CAD HR BLOCK2, KZR-CAD HR BLOCK3 GAMMATHETA, etc.

Resin-based dental restorative material: "iGOS", "TMR-Z Fill 10." etc.

[Instructions]

- Increasing the smoothness of resin surface

(1) Roughening of the resin surface

The surface of composite resin for crown and bridges should be roughened with a carborundum point etc, or sandblasted (about 0.20 to 0.25 MPa) with alumina particles (about 50 μm) to roughen, then wash, and dry.

(2) Coating

Nu:le Coat Liquid is applied to the resin surface and light-cured.

When using Nu:le Coat Gel, the resin surface must be coated with Nu:le Coat Liquid for pretreatment, and after pre-light curing, apply Nu:le Coat Gel and light curing.

- Surface characterization

(1) Roughening of the resin surface

After modifying the shape of the resin surface, fix morphology of the surface with a carborundum point etc, or sandblast (about 0.20 to 0.25 MPa) with alumina particles (about 50 μm) to roughen the surface, then wash, and dry.

(2) Characterization

Shake the bottle of Nu:le Coat Liquid well, then drop a proper amount of Nu:le Coat Liquid on a disposable plate, then apply it thinly on the resin surface and proceed with light curing. If necessary, mix multiple colors of Nu:le Coat Liquids for color adjustment.

- Internal characterization

(1) Build-up resin

Build-up the internal structure (dentin part) with composite resin for crown and bridges.

(2) Characterization

Shake the bottle of Nu:le Coat Liquid well, then drop a proper amount of Nu:le Coat Liquid on a disposable plate, then apply it thinly on the resin surface and proceed with pre-curing. If necessary, mix multiple colors of Nu:le Coat Liquids for color adjustment.

(3) Build-up the surface layer of resin

Build-up the surface layer (enamel part) with composite resin for crown and bridges. For the instructions of composite resin for crown and bridges, please refer to the instructions for use of the product.

- Build-up the resin on PAEK-based materials (PEEK, PEKK, etc.) or polycarbonate

(1) Roughening the surface

Make the surface of the resin rough by a carborundum point etc. or sandblasting (about 0.20 to 0.25 MPa) with alumina particles (about 50 μm). Clean the surface with a steam cleaner and dry.

(2) Application and pre-curing

Apply Nu:le Coat on the surface and proceed with pre-curing.

Because Nu:le Coat Liquid (Clear) has a low viscosity and a thin coat, it needs to be applied and pre-cured twice on the build-up surface (applied twice). Alternatively, mix Nu:le Coat Liquid (Clear) and Nu:le Coat Gel in 1:1 ratio and apply it immediately to the build-up surface and proceed with pre-curing.

(3) Build-up resin and light curing

Follow the Instruction for use of composite resin for crown and bridges.

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

(1) If the light curing is insufficient, it will cause detachment or discoloration in a short time. Therefore, the light-curing device and curing time should follow the conditions described in [Instructions for Use]. When using other light-curing devices or if you have any questions, please feel free to contact YAMAKIN.

(2) If it is difficult to irradiate the light on the whole applied surface, light-cure again from the other directions after the prescribed light curing. According to the light-curing conditions, make the light-curing time longer when the surface is still sticky.

(3) If this product is applied in bright places such as beside the window or under work lights, it will cause curing during the application process. Therefore, it should be used in places away from strong light.

(4) If the resin surface is not roughened before applying this product, the adhesion between this product and the resin will be insufficient, and it will cause detachment. Therefore, roughen the resin surface with a carborundum point or sandblast with alumina particles.

Prior to use, carefully read the instructions manual.

- (5) Since this product might be worn out in a short time, do not apply this product where the occlusal pressure is directly applied.
- (6) Close the cap immediately after use in order to avoid viscosity change because this product contains volatile constituents, which harden under ambient light or when mixing with foreign matters.
- (7) Since the liquid of this product contains volatile components, apply it immediately after taking the standard time which is within 1 minute. When using the disposable plate provided by our company, it should be applied within 4 minutes after taking.
- (8) Depending on the material of the tray, the tray might be dissolved by this product. Therefore, only the disposable plate provided by our company for this product should be used.
- (9) Do not return the collected liquid to the container as it may be hardened.
- (10) When building-up the resin on PAEK-based materials (PEEK, PEKK, etc.), if the Nu:le Coat Liquid (Clear) and Nu:le Coat Gel are mixed in a ratio of 1:1 and left for a while, the viscosity will be increased because the volatile components will volatilize, and become difficult to apply. Therefore it should be applied immediately after mixed. In addition, when the applying area is large, the liquid and the gel should be mixed and applied several times.
- (11) When applying this product to the resin surface, if resin cutting powder, wax components, oil mist and other materials are attached on the resin surface, it may cause detachment, so the resin surface should be cleaned in advance.
- (12) When using this product in the groove, please note that if this product thickens due to liquid accumulation, the curing property will be reduced.
- (13) After applying this product, air drying before light-curing may cause splashing or an uneven surface, so this process should be avoided.
- (14) If the Nu:le Coat Liquid is applied in a large amount, it may cause poor curing under light. Therefore the liquid should be applied thinly (no more than 0.05 mm) and the excess liquid should be wiped off with cotton balls.
- (15) In the case of using a dental curing light, if volatile components remain during light curing immediately after application, it may lead to poor curing. Therefore it is necessary to naturally dry for about 20 seconds after application before curing. In addition, the curing time should be longer when the adherend remains on the surface.
- (16) If the tip of the brush used to apply this product is dried out or the tips are rough, it may cause the entrapping of air bubbles or leave traces of the brush. Therefore a brush with a neat tip should be used.
- (17) The brush used for applying this product should be cleaned with alcohol.
- (18) If this product adheres to mucosal surfaces such as gums and lips before curing, it may cause inflammation. Therefore a rubber dam should be used to prevent contact with the oral mucosa and lips. In case of adhesion to gums, wipe it with cotton balls immediately, and clean it with plenty of running water after the operation.
- (19) This product contains volatile components, so patients should be instructed to breathe through nose when used in the oral cavity.
- (20) Due to the possibility of coloring, patients should be instructed to reduce the consumption of foods with strong coloring (curry, coffee, black tea, wine, etc.) within 3 days after treatment.
- (21) Note that this product may be affected by the curability due to poor quality lamps or dust in the light-curing device.
- (22) Do not use this product and eugenol-based materials together as it may cause poor curing.
- (23) When using the portable dental curing light, the amount of light decreases when it is separated from the irradiation port, so the irradiation port should be as close as possible to the applied surface for irradiation.
- (24) Light irradiators consisting of only blue LED light sources without Violet LED may not be used.
- (25) Apply this product in a place with as little dust as possible, because it may cause foreign matter to enter.
- (26) Do not mix this product with other products.
- (27) When using other medical devices together, review the instructions for use and precautions in the instructions of each product before using it.
- (28) When using this product in the oral cavity, it is necessary to keep the cleaned adhesive surface and the applied surface free from contamination by blood, saliva, hemostatic agents and other materials before light-curing. In case of contamination, the adhesive surface should be cleaned and dried again.
- (29) Note that this product will not adhere to the natural teeth, which may cause detachment if it is adhered.
- (30) Note that when using this product on crowns and resin materials for denture (PMMA, Polycarbonate, etc.) without fillers, applying thick layers may cause cracks (coating thickness less than 40µm, approximate up to 3 layers).
- (31) Note that when using this product on bridges made of PMMA and Polycarbonate without fillers, applying thick layers may cause cracks (coating thickness less than 30µm, approximate up to 2 layers). Especially in areas where the product tends to accumulate.

[Precautions]

- (1) For patients with a history of allergies to pharmaceuticals, food, accessories and chemicals, even if there is no history of allergies to this product and similar products, they should be consulted and used with caution.
- (2) Do not use this product near fire as it is flammable. Also, do not place this product in a place with a high temperature or in direct sunlight.
- (3) Use this product in a well-ventilated place as it contains volatile components (multiple ventilations per hour).
- (4) When polishing the cured product, in order to avoid the impact of dust on the human body, please use a local dust exhaust apparatus and dust masks approved by public institutions to avoid inhalation of dust. Also, wear protective goggles to prevent eye damage.
- (5) Do not use this product beyond the recommended cases, effects, and indications.
- (6) Only qualified personnel may use this product.
- (7) Dispose of this product as a medical waste to prevent infection.

[Important Basic Cautions]

- (1) Patients with allergic symptoms such as rash and dermatitis due to the use of this product should discontinue use and seek medical

advice.

- (2) Operators with allergic symptoms such as rash and dermatitis due to the use of this product should discontinue use and seek medical advice.
- (3) Do not touch directly the uncured material of this product with bare hands. Take protective measures such as wearing plastic gloves and protective goggles to prevent allergy due to contact. If it adheres to the skin, immediately wipe it with alcohol on a cotton ball, and then wash it with plenty of running water. If it gets in your eyes, immediately rinse with plenty of running water and seek the medical attention of an ophthalmologist.
- (4) Be careful not to let this product adhere to oral soft tissues or skin, or get into your eyes. Cover the eyes with a towel to protect the patient from splashing liquid.
- (5) If this product adheres to oral soft tissues or skin, immediately wipe it with alcohol on a cotton ball, and then wash it with plenty of running water. If it gets in your eyes, immediately rinse with plenty of running water and seek the medical attention of an ophthalmologist.
- (6) Be careful not to accidentally swallow this product.
- (7) Since the surface glaze is not permanent, use it as a temporary surface glazing treatment.
- (8) When using a hand-held light irradiator, you should wear protective goggles, as it may hurt your eyes, and do not look directly into the irradiation light.
- (9) The liquid color of this product should be shaken well before use because the coloring material tends to settle. Also, if you leave it on a disposable plate, the coloring material will settle, so mix it with a brush or a spatula before using it.
- (10) If liquid adheres to the nozzle, it may be cured, so wipe it off before closing the cap.

[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 Avoid direct sunlight and fire. 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]

[Single Package]

- Nu:le Coat Gel 2ml
- Nu:le Coat Liquid (Clear) 6ml
- Nu:le Coat Liquid (A plus, B plus, C plus, D plus, White, Brown, Gray, Yellow, Orange, Blue, Red, Pink, Black, Gum and Dark Brown HV) 4ml

[Set Package]

- Intro Set : Clear /Gel/Round Brush x 1/Flat Brush x 1/Disposable Plate x10
- Regular Set : Clear/Gel/White/Gray/Blue/Brown/Round Brush x 1/Flat Brush x 1/Disposable Plate x20
- Full Set : Clear /Gel/White/Gray/Blue/Brown/Yellow/Orange/A Plus/B Plus/C Plus/D Plus/Round Brush x 1/ Flat Brush x 1/Disposable Plate x 30

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