

READ CAREFULLY BEFORE USE

### PRODUCT DESCRIPTION

COAT-IT is light-cured self-adhesive resin coat intended for providing a protective coat to dental restorations. It also inhibits moisture contamination of glass iomoner restorations including RMGI.

# **INDICATIONS FOR USE**

- > To provide a protective surface coat on glass ionomer restorations including RMGI, direct/indirect composite and provisional restoration
- > To inhibit water contamination of glass ionomer restorations including RMGI

## **PRECAUTIONS & WARNINGS**

- Do not use this product on patients with known allergies to this material and/or methacrylate monomer.
- Operators with known allergies to this material and/or methacrylate monomer must not use this product.
- 3. If any inflammation or other allergic reactions occur on either the patient or operator, immediately discontinue use and seek medical advice.
- 4. Avoid any source of ignition as the product is flammable.
- 5. Use in a well ventilated area to avoid inhalation of MMA. If inhalation causes nausea or illness, take rest and keep warm in fresh air.
- 6. Use protective gloves, masks and glasses to avoid sensitization to this product. In case of accidental contact with oral soft tissue or skin, immediately wipe with alcohol moistened cotton ball, and rinse with plenty of water. Medical (dental) gloves provide some protection against direct contact with this material; however some monomers may penetrate through the gloves very quickly to reach the skin. Therefore, should this material come in contact with the gloves, immediately remove them and wash hands with plenty of water.
- Avoid contact with eyes. In case of contact with eyes, immediately flush eyes with plenty of water and seek medical advice.
- 8. Exercise extra caution to avoid inhalation and ingestion of the material.
- Disposable dishes and brushes should be used for only one patient and then discarded at the end of the procedure to avoid cross contamination.
- Use all the dispensed material promptly on one patient to avoid cross infection.
- 11. Use saliva ejector during procedures to eliminate water or saliva.
- 12. Follow the instructions for use of each material, instrument or equipment to be used in conjunction with this product.
- 13. Do not use this product for any purposes other than specifically outlined in these instructions for use.
- Use this product within the expiration date indicated on the package or container.
- (Example  $\square$  YYYY-MM-DD  $\rightarrow$  Year-Month-Date of the expiration date) 15. This product is intended for use by dental professionals only.

### **DIRECTIONS FOR USE**

- 1. Coating for restorations
- 1-1. Preparation of newly placed restorations/existing restorations
  Place the restorative material and set/light-cure following the
  manufacturer's instructions for use of each product. Contour the
  restoration with an abrasive (diamond bur etc), rinse with water and air
  dry. For existing restorations, lightly roughen the restoration surface with
  an abrasive (diamond bur etc), rinse with water and air dry.
  - > COAT-IT should be applied to the roughened restoration surface.
- 1-2. Application of COAT-IT
  - Dispense adequate amount of COAT-IT onto a disposable dish and apply a thin and even coat of COAT-IT to the restoration with a disposable brush.
  - Avoid contamination of the restoration surface during application of this material. If the surface is contaminated by saliva or blood, thoroughly clean the surface with an alcohol moistened cotton ball. Then, dry the surface and reapply the material.

1-3. Light-curing of COAT-IT

Light-cure using a dental light-curing unit immediately after application. In cases where the restored area is large, light-cure in segments. Check if any uncured material remains on the surface with an instrument. If the surface is still tacky, repeat light-curing until the material is cured completely.

- Light-cure immediately after application since this material contains volatile components
- > Dental light-curing unit and light-curing time

Curing unit	Halogen	LED
Curing time	10 sec.	10 sec.
Wavelength	400 - 500 nm	440 - 490 nm
Light intensity	500 mW/cm <sup>2</sup> or more	1000 mW/cm <sup>2</sup> or more

- Operators must use protective glasses or light shielding plate to avoid direct exposure to the curing light. Protect patients' eyes from direct exposure to the curing light.
- Disinfect the light-curing unit with alcohol after each use to avoid cross contamination.
- 2. Inhibition of water contamination of glass ionomer restorations
- 2-1. Filling

Fill glass ionomer cement mixture and create the desired shape following the manufacturer's instructions for use.

2-2. Application of COAT-IT

Dispense adequate amount of COAT-IT onto a disposable dish. When the cement mixture loses luster, apply a thin and even coat of COAT-IT to the restoration with a disposable brush.

2-3. Light-curing of COAT-IT

Light-cure using a dental light-curing unit immediately after application. > Refer to the 1-3 procedures above.

2-4. Contouring

Contour the set glass ionomer restoration with an abrasive (diamond bur etc) following the standard method. Rinse with water and air dry with gentle pressure.

2-5. Application & light-curing of COAT-IT Apply COAT-IT and light cure following the 1-2 and 1-3 procedures above.

#### (Notes)

- When storing this material in a refrigerator, allow it to reach room temperature before use.
- > After dispensing, clean the nozzle tips with a gauze etc. and replace the cap securely.
- Dispense this material immediately before use as it contains volatile components. Use all the material dispensed onto the disposable dish within two minutes after dispensing (when using other dish, use the dispensed material within one minute after dispensing).
- > Do not apply a thick layer of COAT-IT to avoid undesirable effects like bubble entrapment, temperature rise while curing and yellow discoloration.
- > Do not air dry after application to avoid undercuring.
- > Working time is shortened when ambient temperature is higher than 23 °C/73 °F.
- > Do not mix this material with any other material.
- > Tightly close the bottle cap immediately after each dispensing.

### **COMPOSITION**

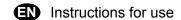
Multi-functional monomer, MMA, phosphonic acid monomer, polymerization initiator and others

### **STORAGE**

> Store at room temperature (1-25 °C/34-77 °F). Avoid high temperatures and high humidity. Keep away from direct sunlight and any source of ignition.

CAUTION: US Federal law restricts this device to sale by or on the order of a dental professional.





01:2017-03 70875



Manufacturer

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Consult instructions for use





Keep away from sunlight and heat

Do not re-use





Temperature limit

Batch code



Use by date



Manufacturer