

HUGE

Enamel Coating Resin

(Instructions for Use)

Version: 01

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U.S. Federal Law restricts this device to sale by or on the order of a dental professional. Prior to use the product, please read the instruction carefully.

GENERAL DESCRIPTION

Enamel Coating Resin as Pit and Fissure Sealant is light cured. It is partially filled for increased strength and durability (Type F), and its viscosity is designed for superior flow on tooth surfaces.

INDICATIONS

Enamel Coating Resin is a visible light curing sealing material for coating on enamel:

- Areas of pit and fissure sealing
- Filling and protecting enamel surface minor defects or suspicious early carious
- Infiltrating into enamel surface and covering underneath enamel structure

CONTRAINDICATIONS

Not to be used if the patient is known to be allergic to any of the materials ingredients.

SIDE EFFECTS

This product or one of its components may cause hypersensitive reactions.

OPERATING PROCEDURES

1. Thoroughly remove pellicle layer and clean enamel surfaces with oil-free cleaning paste.
2. Rinse with copious amounts of water, removing all residual paste from pits and fissures.
3. Isolate treatment area from salivary contamination by placing cotton rolls and/or rubber dam and positioning the patient to avoid pooling of saliva around the treatment site. Dry thoroughly with uncontaminated, oil-free and moisture-free compressed air.
4. Apply phosphoric acid etching gel to the clean, dry treatment site for 20-30 seconds. Rinse with copious amounts of water and air dry. Do not contaminate etched teeth with saliva.
5. If etched surfaces do not appear frosty or chalky white, repeat steps 4-5.
6. A drying agent may be applied to etched

surfaces at this time. Do not disturb these surfaces. Salivary contamination must be avoided at this critical point. If saliva contamination occurs, wash and dry surface, and etch again with phosphoric acid etching gel for 10 seconds. Wash and dry again and proceed.

7. Place a 25-gauge applicator tip on the Type F syringe and carefully start flow of the Enamel Coating Resin or use a micro-applicator (brush) for the Type NF Enamel Coating Resin.
8. Apply Enamel Coating Resin to the pits and fissures. Flow the material from cusp to cusp, but do not cover the marginal ridges. It is better to apply more than too little.
9. Light cure each surface for 10 seconds, depending on light you are using.
10. Inspect the sealant surfaces. If coverage is incomplete, apply more Enamel Coating Resin. If tooth has been contaminated, etch again for 10 seconds, wash, dry and then place additional Enamel Coating Resin.
11. Check occlusion and adjust as required.

NOTE

· Refer to outer package for expiration date. Do not use after expiration date.

- For dental use only. Do not use for indications or applications that are not specifically noted in the instructions for use.
- Follow the Operating Procedures when using.
- Notification of any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in your country.

PRECAUTIONS

- Uncured methacrylate resin may cause contact dermatitis and damage the pulp. Avoid contact with skin, eyes and soft tissue. Wash thoroughly with water after contact.
- Dispensing Tips or Disposable Micro applicators are for single use only, to prevent cross-contaminations between patients.
- Disposal must be made in accordance with local regulations.
- Keep material out of children's reach.
- This product is easy to polymerization early if exposed to natural light or artificial light. Do not place under strong light during use.
- Recommend to store in a refrigerator when not in use for better life.

STORAGE

- Store Enamel Coating Resin at 2-25°C in cool, dry place and away from direct light. Use the material at normal room temperature.
- Shelf life: 3 years from date of manufacture

WARRANTY

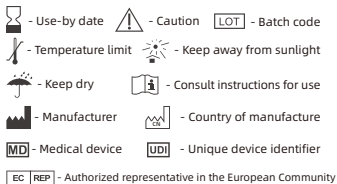
Rizhao HuGe Biomaterials Company, Ltd. warrants this product is free from defects in material and manufacture.

HUGE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is defective within the warranty period, your exclusive remedy and HUGE's sole obligation shall be repair or replacement of the HUGE product.

LIMITATION OF LIABILITY

Except where prohibited by law, HUGE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

SYMBOLS FOR USE IN THE LABELING



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