

Enamel Coating Resin

(Instructions for Use)

Version: 03
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U.S. Federal Law restricts this device to prescription use only. Prior to use the product, please read the instruction carefully.

General Description

Proseal Enamel Coating Resin is a light-curing fissure sealant. Type F contains fillers featuring fluoride release. Type NF doesn't contain fillers featuring better fluidity but without fluoride release.

Composition

Type F: The monomer matrix consists of TEGDMA and UDMA. The fillers are highly dispersed silicon dioxide and Glass ion powder. Additional contents are titanium dioxide, stabilizers and catalysts.

Type NF: The monomer matrix consists of TEGDMA, UDMA, as well as titanium dioxide. Additional contents are stabilizers and catalysts.

Indications

Proseal Enamel Coating Resin is a light curing material for sealing the enamel pits and fissures of teeth.

Contraindications

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

Side effects

In individual cases, contact allergies may occur. According to today's standard of knowledge, systemic side effects are not known.

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 applicator tip on the Type F syringe and carefully start flow of the Proseal Enamel Coating Resin; or drop Type NF Proseal Enamel Coating Resin into the Mixing-well, and then use a micro-applicator (brush) for the Type NF Proseal Enamel Coating Resin.
8. Apply Proseal 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-curing intra-orally: This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of 800mW/cm² in the 400-500nm range. Hold the light guide tip as close to the restorative as possible during light exposure

(the irradiation distance is less than 5mm). Cure each surface for 10 seconds.

10. Inspect the sealant surfaces. If coverage is incomplete, apply more Proseal Enamel Coating Resin. If tooth has been contaminated, etch again for 10 seconds, wash, dry and then place additional Proseal 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, Disposable Micro applicators and Mixing-well 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.

• If one of the following is noted, it is a sign that the material is losing its intended efficacy and should no longer be used:

- Nothing comes out of the syringe or bottle although there is material left inside.
- Solid or gel-like coagulation is detected in the liquid when dispensed.
- Threads are visible in the material during application with the micro brush.
- Select the light unit curing unit in accordance with local medical device standard and use them according to its instructions for use.
- Carry out daily maintenance as prescribed by dentist.
- For professional use only.

Storage

- Store Proseal 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

Packages

- 1.Proseal Enamel Coating Resin
- 2.Accessories: Dental dispensing tips for Type F; Disposable Micro applicator (Micro-brush) and Mixing-well for Type NF.

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

	— Caution
	— Temperature limit
	— Keep away from sunlight
	— Keep dry
	— Consult instructions for use
	— Manufacturer
	— Use-by date
	— Batch code
	— Unique device identifier
	— Country of manufacture
	— Medical device
	— Authorized representative in the European Community
	— Caution: U.S. Federal Law restricts this device to sale by or on the order of a dentist or professionals.



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包材编号/物料名称	4000000004180 国外窝沟封闭说明书沪鸽版 02
包材材质要求	60g纸
颜色	彩色印刷
其他	尺寸：148mm×105mm