

Hydrofluoric Acid Etching Gel (Instructions for Use)

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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

HuGe Hydrofluoric Acid Etching Gel is a flowable gel with excellent water solubility and miscibility. Using a disposable dispensing tip, Hydrofluoric Acid Etching Gel can be directly applied onto the porcelain restoration surface. Its color is red, which can be identified easily on porcelain surface with contrast.

Hydrofluoric Acid Etching Gel is used as an auxiliary material in a dental bonding procedure followed by the use of Huge Ceramic Coupling Agent and Light Cure Dental Adhesive.

INDICATIONS

Used for etching of various types of resin bonded porcelain/ceramic restorations (conventional feldspathic porcelain, Leucite glass ceramic, lithium disilicate, zirconia reinforced lithium silicate glass-ceramic, fluorapatite glass ceramic, etc.) prior to the bonding and cementation procedure.

MAIN COMPOSITION

Water, hydrofluoric acid, food grade thickening and coloring agents.

Accessories: Dispensing Tips

CONTRAINDICATIONS

Not for etching of tooth surface.

OPERATING PROCEDURES

1. Never use excessive force on syringe plunger to dispense etch which may lead to over dispensing of the material. If resistance is felt, replace current tip with a new tip and check flow extra-orally.
2. Apply the HF gel onto the entire internal surface of the porcelain restoration, and wait for 60 seconds. One may use the tip to stir the gel a bit in order to refresh the gel contacting the porcelain surface to have a complete etch effect during the waiting time.
3. Wash off the HF gel with a jet of stream water for 10 seconds and dry with contamination-free air.
4. Proceed to the application of HuGe Ceramic Coupling Agent (see the instruction for Use of the material).

NOTE

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

CAUTIONS

- Contains HF acid. Avoid contact with skin, eyes and soft tissue. In case of contact with skin or eyes, flush immediately with water. Get medical attention for eyes. Do not take internally.
- Dispensing Tips are for single use only, to prevent cross-contaminations between patients.
- If there is spill of the HF gel, pour sufficient amount of base natured chemicals such as Baking Soda, Calcium Hydroxide, etc. to the spilled material to neutralize the acid immediately. Then clean the site with water, or wipe it off with proper materials and discard following local environmental regulations.
- Wear acid resistant gloves and eye protection goggles when handling the HF acid gel.

- Keep away where children may reach.

STORAGE

- Store Hydrofluoric Acid Etching Gel at 2-25°C and away from direct light. Use the material at normal room temperature.
- Shelf life: 2 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.

LI MITATION 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

-  - Use-by date
-  - Caution
-  - Batch code
-  - Temperature limit
-  - Country of manufacture
-  - Consult instructions for use
-  - Keep dry
-  - Keep away from sunlight
-  - Unique device identifier
-  - Authorized representative in the European Community
-  - Medical device
-  - Manufacturer
-  - Warning; Corrosive substance

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