

HUGE

Ceramic coupling Agent

(Instructions for Use)

Version: 01

Date of Issue: Oct 15, 2021

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.

INDICATIONS

Ceramic Coupling Agent serves as priming agent and is used to create a durable adhesion between luting composites and glass/oxide ceramic, metal, composite and fiber-reinforced composite restorations.

ACCESSORIES

Disposable Micro applicator (Micro-brush),
Mixing-well

CONTRAINDICATIONS

· Not for exposed pulp or pulpitis needing treatment.

SIDE EFFECTS

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

OPERATING PROCEDURES

1. Apply sufficient amount of the Ceramic Coupling Agent to the inside of the etched or

sandblasted porcelain restorations or sandblasted ceramic structures (Zirconium Oxide, Aluminum Oxide, etc.).

2. Leave it on for 60 seconds. DO NOT TOUCH THE PRIMED SURFACE WITH YOUR HANDS.

3. Dry the coupling agent with a jet of air.

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.

PRECAUTIONS

- The Ceramic Coupling Agent contains flammable solvents. Keep away from sources of ignition.
- After dispensing the Ceramic Coupling Agent from the container, close the cap immediately to prevent the quick evaporation of the solvent.
- 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.
- Brush Tips are for single use only, to prevent cross-contaminations between patients.
- Disposal must be made in accordance with local regulations.
- If one of the following is noted, it is a sign that the material is losing its bonding efficacy

and should no longer be used:

- nothing comes out of the container when squeezed although there is material felt inside.
- resin with silky appearance is visible during the application.

STORAGE

- Store the material at 2-25°C, keeping the cap tightly closed, away from direct light exposure. Use it at normal room temperature.
- Shelf life: 2 years from date of manufacture

PACKAGES

1. Ceramic Coupling Agent
2. Disposable Micro applicator (Micro-brush)
3. Mixing-well
4. Packaging specifications: 1ml, 3ml, 5ml, 6ml

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

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

Rizhao HuGe Biomaterials Company, Ltd.

No.2 North Zhaoyang Road, District of Donggang,
Rizhao City, Shandong Province, China 276800
www.hugedental.com marketing@hugedental.com

 MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

