Ceramic Coupling Agent

(Instructions for Use)

Version: 04
Date of Issue: November 26, 2025

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 for Use

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.Preliminary treatment of bonding surface of ceramic restoration: Dental technicians or dentists should perform pre-etching, hydrofluoric acid etching or other recommended treatment on the bonding surface according to the respective restoration product instructions, then thoroughly clean before clinical use.
2.Take 1-3 drops of Ceramic Coupling Agent (adjust as needed based on the size of restoration) into Mixing-well, dip Ceramic Coupling Agent with the brush tip in a sufficient amount, and evenly apply it to the clean surface of the ceramic restoration. It can be applied multiple times to ensure the entire bonding surface to be "moist".
3.Leave it on for 60 seconds. DO NOT TOUCH THE PRIMED SURFACE WITH YOUR HANDS.
4.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℃, keeping the cap tightly closed, away from direct light exposure. Use it at normal room temperature.
• Shelf life: 2 years from date of manufacture

Warranty
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
LOT -- Batch code
-- Use-by date
MD -- Medical device
-- Manufacturer
CN -- Country of Manufacture
EC REP -- Authorized representative in the European Community
UDI -- Unique device identifier
Rx ONLY -- Caution:U.S.Federal Law restricts this device to sale by or on the order of a dentist or professionals

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