

TrusFIL-Flow Flowable Composite Restorative

(Instructions for Use)

Version: 02

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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

Flowable Composite Restorative is a visible light curing dental restorative material intended to restore carious lesions or structural defects in teeth in combination of a bonding agent and with or without other materials such as luting, etching agents, cavity liners, flowable composites and others commonly used in a tooth restoration. The principal organic components are mixtures of dental methacrylate resins (Bis-GMA, TEGDMA, EBPADMA). The inorganic filler (Silane treated barium glass, Ca-Zr-Silicate) loading is about 46% by volume having particle size range of about 0.01 to 3 microns. It is packaged in syringes deliverable through a dispensing tip.

CLASSIFICATION

Type 1 Class 2 Group 1

SHADE SELECTION

The appropriate shade(s) of Flowable Composite Restorative could be selected using a standard VITAPAN® classical shade guide.

INDICATIONS

Flowable Composite Restorative is a visible light curing dental restorative material indicated for:

- Class III and V restorations.
- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations).
- Base/liner under direct restorations.
- Repair of small defects in indirect restorations.
- Pit and fissure sealant.
- Undercut blackout.
- Repair of resin and acrylic temporary restorations.

CONTRAINDICATIONS

- Patient known to be allergic to methacrylate resins should be avoided to use this product.

SIDE EFFECTS

- THIS PRODUCT OR ONE OF ITS COMPONENTS MAY CAUSE HYPERSENSITIVE REACTIONS.

OPERATING PROCEDURES

1. Prepare tooth as usual
2. Applying Bonding Agent

In terms of reaction principle, the Flowable Composite Restorative is theoretically compatible with all commercially available clove-oil-free resin adhesives and ceramic coupling agents. Please refer to the instructions of the specific bonding agent you are using.

- Note: It is recommended to perform silanization when repairing the porcelain restoration, and then apply the adhesive.

3. Applying the Flowable Composite Restorative

Applying the Flowable Composite Restorative directly with the bent 20G tip supplied with the kit. Be sure to cover the preparation site thoroughly with the material. Do not build increments of more than 3 mm thickness for proper light curing*. Pull back on syringe plunger after use to prevent material seepage. Remove the used tip and replace it with the original cap; do not leave the used tip on the syringe.

- Note: It is important that every time when placing a bent dispensing tip onto the syringe, be sure the tip is all the way thread into the plastic hub and locked in. It is best to try to dispense the material through the tip outside the mouth a bit before applying the material intra-orally to prevent the tip popping up inside the mouth and spill the material accidentally.

4. Light Curing

For conventional curing lights (output between 600 ~1000 mw/cm²), cure each layer for 10 seconds. Cure final restoration an additional 20 seconds per surface. For high output lights (> 1000 mw/cm²), cure each layer for 5 seconds and cure final restoration an additional 10 seconds per surface.

5. Trimming, Finishing, & Polishing

Using conventional method and materials for shaping, trimming and finishing. Using non-abrasive polishing disc with polishing paste to achieve the maximum shine.

· Note: Due to the opacity, build the universal opaque or opaque shades in increments not more than 1 mm thickness to ensure effective polymerization.

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.
- Dispose in accordance with local regulations.
- Dispensing Tips are for single use only, to prevent cross-contaminations between patients.
- This product is easy to polymerization early if exposed to natural light or artificial light. Do not place under strong light during use.
- Keep out of the reach of children.
- Recommend to store in a refrigerator when not in use for better life.
- Carry out daily maintenance as prescribed by dentist.
- For professional use only.
- Do not use provisional cements containing eugenol, as these materials may interfere with the curing of the Flowable Composite Restorative.
- 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 although there is material left inside.
 - Solid or gel-like coagulation is detected in the pastes when dispensed.

STORAGE

- Store Flowable Composite Restorative 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


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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

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