HUGE

TrusFIL Universal Composite Restorative

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

TrusFIL Universal Composite Restorative is a visible-light activated, restorative composite designed for use in anterior and posterior restorations. The principal organic components are mixtures of dental methacrylate resins (Bis-GMA, TEGDMA, EBPADMA). The inorganic filler loading is about 54% by volume having particle size range of about 0.01 to 2 microns. It is packaged in syringes and single-dose capsules. Single-dose delivery is intended for single patient (single use) only to prevent cross-contamination between patients. All shades are radiopaque.

Classification

Type 1 Class 2 Group 1 and Group 2

Shade Selection

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

Indications

TrusFIL Universal Composite Restorative is a visible light curing dental restorative material indicated for:
- Direct anterior and posterior restorations (including occlusal surfaces);
- Core Build-ups;
- Splinting;
- Indirect restorations including inlays, onlays and veneers.

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.

Physical Properties

Compressive Strength (MPa)	**＞200**
Flexural strength (MPa)	**≥100**
Water sorption (μg/mm^3)	**≤40**
Solubility (μg/mm^3)	**≤7.5**

Operating Procedures

1.Operatory Preparation

•Prophy: Teeth should be cleaned with pumice and water to remove surface stains.
•Shade Selection: Before isolating the tooth, select the appropriate shade(s) of restorative material using a standard VITA Lumin® shade guide.
•Isolation: A rubber dam is the preferred method of isolation. Cotton rolls plus an evacuator can also be used.

2.Direct Restorative

•Applying Bonding Agent: Please refer to the instructions of the specific bonding agent you are using.
•Optionally applying a cavity liners with restorative materials such as a flowable resin composite, a resin-modified glass ionomer or a conventional glass ionomer cement. Please refer to the instructions of the specific materials you are using.
•Dispensing the Composite: Follow the directions corresponding to the dispensing system chosen.
- Syringe: Dispense the necessary amount of restorative material from the syringe onto the mix pad by turning the handle slowly in a clockwise manner. To prevent oozing of the restorative when dispensing is completed, turn the handle counterclockwise a half turn to stop paste flow. Immediately replace syringe cap. If not used immediately, the dispensed material should be protected from light.
- Single-Dose Capsule: Insert capsule into the restorative dispenser. Refer to separate restorative dispenser instructions for full instructions and precautions. Extrude restorative directly into cavity.
•Applying TrusFIL Universal Composite Restorative and light-curing intra-orally: This product is intended to be cured by exposure to the LED light with a minimum intensity of 600mW/cm²in the 400-500 nm range. Cure each increment by exposing its entire surface to a high intensity visible light source. Hold the light guide tip as close to the restorative as possible during light exposure.

		Cure Time	
Shades	Increment depth	All LED lights (with output 600-1000 mW/cm^2)	For high output lights (1000-2000 mw/cm^2)
For lighter shades (A1, A2, B1, B2, C1, Enamel, Translucent)	2.0 mm	20 sec.	10 sec.
For darker shades (Dentin, Body other than those lighter shades described above)	1.5 mm	40 sec.	20 sec.

3.Trimming, Finishing, & Polishing:

•Gross contouring may be accomplished using high speed diamond and 12 or 16 fluted carbide burs.
•Finer contouring/surface finishing may be accomplished with various coarse polishing disks, rubber points/cups and finishing strips to create a smoother surface. To achieve a final polish, use polishing disks, starting with the coarse grits and moving down to the super fine grit.

4.Indirect Restorative

•Make impressions of the preparations and pour the impression with die stone per laboratory routine procedure.
•Section out the preparation and prepare the die following laboratory procedures.
•Add the first increment of composite to the floor of the preparation, stay short of the margins, and follow the cure recommendations described in the Direct Restoration section.
•Place and cure additional increments of composite. Allow for the last increment (incisal) to include the contact areas.
•Place the die back into the articulated arch. Add the last increment of composite to the occlusal surface. Overfill very slightly mesially, distally, and occlusally. This will allow for the mesiodistal contacts and the proper occlusal contact when the opposing arch is brought into occlusion with the

uncured increment. Light cure for only ten seconds, then remove the die to prevent adhering to adjacent surfaces.
Finish the curing process following the cure times in the Direct Restoration section.
•With the occlusal contacts already established, begin removing the excess composite from around the points of contact. Develop the inclines and ridges as per remaining occlusal anatomy.
•Care must be taken when removing the prosthesis from the die. Break off small amounts of the die from around the restoration, the die stone should break away
•cleanly from the cured restoration, until all of the restoration is recovered.
•Using the master die, check the restoration for flash, undercuts, and fit. Adjust as necessary, and then polish as noted above in Direct Restorative.
•Clean the prosthesis in a soap solution in an ultrasonic bath and rinse thoroughly.
•Cementation: Cement the prosthesis using a resin cement system following manufacturer' s instructions.

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.
•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.

Storage

•Store Universal Composite Restorative at 2-25℃, away from direct light with the cap closed tightly. Use the material at normal room temperature.
•Shelf life: 3 years from date of manufacture

Warranty

Rizhao HuGe Biomaterials Co., 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

 —— Manufacture

 —— Use-by date

LOT —— Batch code

EC REP —— Authorized representative in the European Community

UDI —— Unique device identifier

——Country of manufacture

MD —— Medical device

CE 1639


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