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# Renamel® BULKfill™ | Light-Cured BULKfill Composite

## INSTRUCTIONS FOR USE

### DESCRIPTION

**Renamel BULKfill** is a light-cured, microhybrid filled, radiopaque dental filling material for direct restorations in posterior teeth, referenced to EN ISO 4049 (Type 1/Class 2/ Group 1). **Renamel BULKfill** cures with LED or Halogen light at wavelength range of 400 – 500 nm and can be applied in layers of up to 4 mm.

Renamel BULKfill has a compressive strength of > 300 MPa, flexural strength > 90 MPa, radiopacity > 100% Al.

### COMPOSITION

**Renamel BULKfill** contains Bis-EMA, Bis-GMA and UDMA (27%). The fillers contain barium glass and silicon dioxide. (72-73% by weight and 51-52% by volume). Initiators, stabilizers and pigments are additional ingredients (< 1%). The particle size of the fillers range from 0.01 – 3 micron with a mean particle size of 0.7 microns.

### INDICATIONS FOR USE

1. Direct Posterior Restorations (including occlusal surfaces)
2. Replacement of individual cusps
3. Base-liner under direct restorations.
4. Restorations of deciduous teeth
5. Class V restorations (cervical caries, root erosion, wedge-shaped defects)

### DISPENSING COMPOSITE MATERIAL

#### Unit Dose Delivery:

- Insert unit dose into dispensing gun and dispense composite material. Dispose of unit dose after use.

### PLACEMENT DIRECTIONS

#### ① Cavity preparation

Place rubber dental dam or use appropriate isolation to prevent contamination during dental procedure.

Pre-wedge if interproximal restoration is anticipated.

Create cavity preparation so that caries are removed and all residual amalgam or restorative material is eliminated.

Use pulpal protection, based on manufacturer's recommendations, as necessary.

#### ② Placement of matrix

If treating interproximal lesions, place contoured matrix band(s) and wedge(s). Sectional ring(s) may be used if deemed necessary.

#### ③ Adhesive application

Follow manufacturer's instructions for adhesive technique. Absolute isolation is critical for optimum adhesion.

Place dental adhesive of choice, such as Cosmedent's Complete™ and polymerize.

#### ④ Renamel BULKfill placement

Place increment of Renamel BULKfill, filling the restorative space from cavity floor in a horizontal layer. Limit depth of composite to no more than 4 mm per increment. As a highly filled microhybrid composite, Renamel BULKfill can be used as the surface layer of the posterior restoration.

#### ⑤ Curing

Renamel BULKfill is intended to be cured by exposure to halogen or LED light with a minimum intensity of 550 mW/cm<sup>2</sup> in the 400-500 nm range (e.g. Optilux® or SiriusMAX®). Cure each increment by exposing its entire surface to a high intensity light source. Hold the light guide tip as close to the restoration as possible during light exposure.

If necessary, place additional layers to complete restoration.

After placing the last increment, place a layer of glycerine (i.e. Oxygone™) to eliminate the oxygen inhibited layer and ensure optimal polymerization of the surface composite, which will enhance easier finishing and polishing.

#### Curing Time for each surface:

Halogen lights (e.g. Optilux 550 – 1000 mW/cm<sup>2</sup>) 40 sec

LED lights (e.g. Sirius MAX > 1000 mW/cm<sup>2</sup>) 20 sec

**Note:** For Class II restorations, remove the matrix band prior to the buccal and lingual curing steps.

#### ⑥ Contour and Polish

Adjust composite using fluted carbide or fine diamond burs to appropriate occlusal contacts.

Polish surface of composite utilizing a Nano polishing system followed by an aluminum oxide polishing paste (i.e. Enamelize™) with a Felt Flexi-point.

For more detailed polishing techniques, please visit Cosmedent's Learning Center at [Cosmedent.com/Learning\\_Center](http://Cosmedent.com/Learning_Center) or call a Cosmedent Customer Care Representative at 800-621-6729.

### USEFUL TIPS FOR PLACEMENT

1. The use of titanium-coated instruments is desired to prevent composite pull-back.
2. Use a **Cosmedent 8A** or **8AL (long or short blade)**, or **Cosmedent's Multi-Use**, or a G3 for application and general

shaping of the material, and the IPCT or IPCL (long or short blade) for finite refinements.

3. **Cosmedent's Posterior titanium-coated instruments** are excellent for placing and developing contour in posterior restorations.
4. Use a Caliper instrument for measurements.
5. Make sure your patient removes all makeup prior to treatment.
6. When applying composite place convenience form in one piece, then sculpt off excess. This is much easier than placing too little and then adding more.

#### HYGIENE / DISINFECTION

- Do not reuse a unit dose compule.
- Disinfection of the unit dose dispenser can be carried out using a commercially available disinfecting solution.
- All instruments used should be thoroughly washed and autoclaved.

#### RENAMEL BULKFILL STORAGE

- Keep **Renamel BULKfill** at room temperature (approximately 39 – 77 °F; 4 – 25 °C).
- Do not use after expiration date.
- Keep away from sunlight.
- Keep material out of reach of children.

#### **R<sub>x</sub>** IMPORTANT PRODUCT INFORMATION

Federal (U.S.) law restricts this device to sale by or on the order of a dentist.

**Note:** This product was developed for use in the dental sector and should be used in accordance with the instructions for use. The manufacturer does not accept liability for damage caused by its use for any other purpose. The user is also obliged to accept responsibility for checking before use that the material is suitable and can be used for the intended purpose, particularly if this is not listed in the instructions for use.

#### DISPOSAL INSTRUCTIONS

Dispose of contents/ container in accordance with local regulation.

#### CONTRAINDICATIONS

Do not use if a patient is known to be allergic to any of the ingredients of **Renamel BULKfill**.

Due to esthetic reasons, Renamel BULKfill is not suitable for Class III and Class IV restorations.

#### SIDE EFFECTS

Can cause irritation in sensitive patients.

To avoid possible irritation of the pulp, areas close to the pulp should be protected with a suitable pulp- /dentin protector (selectively apply a calcium hydroxide-based preparation in areas close to the pulp and cover it with a suitable cavity liner.

#### INTERACTIONS

Do not use **Renamel BULKfill** in combination with eugenol containing materials, as these can impede the polymerization process.

#### NOTICE

During time-consuming procedures, avoid overexposure from the operatory light to protect against premature polymerization of the material. The light curing unit must be maintained and calibrated according to the manufacturer's specifications.

#### WARNING

**Renamel BULKfill** contains Urethane dimethacrylate. May cause an allergic skin reaction. Wear protective gloves. In case of contact with the eyes, rinse immediately with plenty of water and seek medical attention.

#### PACKAGING

**Renamel BULKfill** is available in packages of 20 Unit Dose compules of 0.25 grams each.

#### SHADES

A1, A2, A3, A3.5, B-Zero, B1, C3, D2.



Batch number



Item number



Shelf life



Do not re-use



Observe directions for use



Distributor



Recommended storage temperature



Manufacturer



Keep away from light



Warning



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