

# FluoroCore® 2

## Fluoride-Releasing Dual Cure Core Build-up Material

### DIRECTIONS FOR USE - ENGLISH

**Caution:** U.S. federal law restricts this device to sale by or on the order of a dentist.

FluoroCore® 2 Fluoride-Releasing Dual Cure composite core build-up material consists of two-components, base and catalyst, which when mixed form a dual-cured, highly filled, composite resin core build-up material. FluoroCore® 2 core build-up material uses a bio-compatible urethane resin and is supplied in two shades, blue and tooth colored. The blue shade permits clear differentiation of the core material from tooth structure. The tooth colored shade can be used where esthetics and show-through of the core are of primary concern. FluoroCore® 2 core build-up material is available in a convenient dual-barreled syringe. This delivery system simplifies direct, precise intra-oral delivery and minimizes product waste.

The use of a compatible dentin/enamel adhesive prior to the placement of FluoroCore® 2 core build-up material is mandatory. FluoroCore® 2 core build-up material is compatible with numerous dentin/enamel adhesive systems including ProBOND® All purpose Bonding agent, Prime&Bond® NT™ Dual Cure Universal Dental Adhesive System and Xeno® IV Dual Cure Self-Etch Dental Adhesive system. Other dentin/enamel adhesive systems may be used at the discretion and sole responsibility of the dental practitioner.

### COMPOSITION

Urethane Dimethacrylate; Di- & Tri-functional Methacrylates; Barium Boron; Fluoroaluminosilicate Glass; Camphorquinone (CQ) Photoinitiator; Photoaccelerators; Silicon Dioxide; Benzoyl Peroxide

### INDICATION FOR USE

Vital or non-vital tooth core build-up (replacement of existing restorations and/or lost tooth structure) as a base prior to fabricating an indirect restoration.

### CONTRAINDICATION

The FluoroCore® 2 core build-up material is contraindicated in patients with a history of allergic reaction to methacrylate resins.

### WARNINGS

1. FluoroCore® 2 core build up material contains polymerizable methacrylate monomers. Avoid prolonged or repeated contact with skin (allergic contact dermatitis), oral soft tissues, and eyes. Avoid prolonged inhalation. Do not take internally.  
**Eye contact:** FluoroCore® 2 core build up material contains methacrylates which may be irritating to eyes. Before using this product wear protective glasses as well as covering the patient's eyes to protect from material. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.  
**Skin contact:** FluoroCore® 2 core build up material contains polymerizable monomers which can cause skin sensitization (allergic contact dermatitis) in susceptible individuals. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water after contact. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention.  
**Oral mucosa contact:** Avoid contact with oral soft tissues. If accidental contact occurs, flush mucosa with plenty of water and expectorate water. If sensitization of mucosa persists, seek medical attention immediately.  
**Ingestion:** Do not swallow or take internally. If accidental swallowing occurs, drink lots of water. If nausea or illness develop, seek medical attention immediately. Contact regional Poison Control Center if necessary.
2. FluoroCore® 2 in dual-barreled syringe should extrude easily: DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material.

### PRECAUTIONS

1. This product is intended to be used only as specifically outlined in the *Directions For Use*. Any use of this product inconsistent with the *Directions For Use* is at the discretion and sole responsibility of the practitioner.
2. Contact with saliva and blood during composite placement may cause failure of the restoration. Use of rubber dam or adequate isolation is recommended.
3. Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
4. Eugenol-containing dental materials should not be used with FluoroCore® 2 core build-up material because they may interfere with hardening and cause softening of the polymeric components of the materials.
5. The FluoroCore® 2 core build-up material base paste contains photoinitiators for visible

- light cure. Proceed immediately once material has been placed or protect from exposure to ambient light.
6. Syringe should be tightly closed by replacing the original cap immediately after use.
7. FluoroCore® 2 core build up material is intended to be used as a dual cure product. To obtain optimal curing follow the *Step-by-Step Instructions*. Self-cured, dual cured and light cure methods are integrated into the procedural steps.
8. FluoroCore® 2 should be mixed in equal volumes directly through the supplied mix tips for optimum performance. Variations from this 1:1 ratio may adversely affect working time and compromise final physical properties. Dispensing and mixing other than through the supplied mixing tips is not recommended.
9. Use only in well ventilated areas.
10. Variable in-vitro data exist regarding use of light-cured-only adhesives such as Prime&Bond® NT™ Light Cured Dental Adhesive or Xeno® IV One Component Light Cured Self-Etching Dental Adhesive without Self Cure Activator in conjunction with dual cured or self-cured composite restorative materials such as FluoroCore® 2 core build up material in limited or no light curing applications. Chemical/Product incompatibility may adversely affect product efficacy, leading to premature restoration failure.
11. **Storage and Shelf Life:** FluoroCore® 2 core build up material syringes should be stored with the original cap only, kept out of direct sunlight and stored in a well ventilated place at refrigerated temperature between 2°C/35°F and 8°C/46°F when not in use. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

### ADVERSE REACTIONS

1. Product may irritate the eyes and skin. **Eye contact:** irritation and possible corneal damage. **Skin contact:** irritation or possible allergic response. Reddish rashes may be seen on the skin. **Mucous Membranes:** inflammation, edema, sloughing. (See *Warnings*)
2. Product may cause serious health effects if ingested. (See *Warnings*)
3. Inhalation of vapors may cause varying degrees of damage to the affected tissue and also increased susceptibility to respiratory illness. (See *Precautions*)
4. The following medical conditions are generally aggravated by exposure: Individuals with pre-existing skin disorders, eye problems or impaired liver, kidney and respiratory functions.

### STEP-BY-STEP INSTRUCTIONS

1. **Cleaning and Preparation of Tooth**
  - 1.1 Finish preparation by removing existing restorations and/or caries.
  - 1.2 Clean freshly cut enamel and dentin with water spray and air dry. Do not desiccate dentin.
  - 1.3 Place pin, post or matrix as needed.
2. **Pulp protection, Tooth Conditioning/Dentin Pretreatment, Adhesive Application**

Refer to applicable manufacturer's directions for pulp protection, tooth conditioning and/or adhesive application. Once the surfaces have been properly treated, they must be kept uncontaminated. Proceed immediately to placement of FluoroCore® 2 core build up material.
3. **Dispensing and mixing FluoroCore® 2 Core Build-Up Material** – dual barreled syringe
  - 3.1 Prior to use, remove from refrigerator and bring to room temperature.
  - 3.2 Remove syringe cap and dispense and discard a small amount of material from the dual barreled syringe. Be sure material is flowing freely from both ports. Holding syringe vertically, carefully wipe away excess so base and catalyst do not cross contaminate and cause obstruction of the ports. Save syringe cap for replacement following use.
  - 3.3 Install a mixing tip on the cartridge by lining up the v-shaped notch on the outside of the mix tip with the v-shape notch on the syringe flange. Turn colored mix tip cap 90 degrees in a clockwise direction to lock in place on syringe.
  - 3.4 Gently depress syringe plungers to begin the flow of material. DO NOT USE EXCESSIVE FORCE. If force is encountered, remove syringe from operating field, remove and discard mix tip. Check for obstruction and confirm material is flowing from both syringe barrels. Wipe barrels and install new mix tip as outlined above. Dispense a small amount through the mix tip onto a mixing pad and discard.
  - 3.5 Proceed immediately to Placement, step 4.
4. **Placement of FluoroCore® 2 Core Build-Up Material**

FluoroCore® 2 produces a syringable mixed consistency for direct placement using the dual barreled syringe and a banded matrix retainer or clear crown form. Alternatively, mixed material may be expressed onto a clean paper pad and manually placed with the operator's placement instrument(s) of choice. Working time of mixed material at room temperature (22°C/72°F) is approximately 1'30" (one minute thirty seconds) when protected

from ambient light. Any of the following placement techniques are acceptable. The preferred method is to use both visible light and chemical self cure (see step 4 .3 Dual Cure).

- 4.1 *Visible Light Cure:* Place mixed material directly in 2-3mm increments and light cure increment for 20 seconds.<sup>1</sup>
- 4.2 *Chemical Self Cure:* Place large increment(s) or load mixed material into a clear crown form and seat onto the preparation. Allow to self-cure approximately 3-4 minutes. Visible light curing<sup>1</sup> of external surface is optional, but advisable.
- 4.3 *Dual Cure:* After placing the first 2-3mm increment, and visible light curing for 20 seconds<sup>1</sup>, large increments may then be placed or material loaded into a clear crown form, seated onto the preparation and allowed to self cure. Visible light curing of external surface is optional, but advisable.

**Typical Working Properties:**

Minimum Work Time (22°C): . . . . . 1 minute 30 seconds  
Self Cure Set Time (37°C): . . . . . 3-4 minutes  
Light Cure Set Time: . . . . . 20 seconds<sup>1</sup> (3mm depth)

**5. Finishing the FluoroCore® 2 Core Build-Up Material**

After removal of matrix, a surface light cure of the material for an additional 20 seconds<sup>1</sup> is recommended. Initial crown preparation (gross reduction) may begin immediately using rotary instruments. If used per Step 4.2 or 4.3, utilizing chemical self cure, greatest bulk hardness is obtained 6 minutes after start of mixing at which time the final preparation may be completed.

**CLEANING AND DISINFECTION**

For dual-barreled syringe, remove used mix tip and discard appropriately. Replace original syringe cap prior to storing. The dual-barreled syringe may be cleaned by scrubbing with a disposable towel soaked with hot water and soap or detergent.

The syringe, if exposed to spatter or spray of body fluids or if touched by contaminated hands or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are EPA-registered as tuberculocidal. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide and dual or synergized quaternary ammoniums are approved disinfectants. Disinfect the syringe by spraying the syringe with any recommended hospital-level surface disinfectant for the contact time recommended by the disinfectant manufacturer for optimum results. Spraying with glutaraldehyde is not recommended. Some phenolic-based agents and iodophor-based products may cause surface staining. Agents containing organic solvents, such as alcohol, may tend to dissolve the plastic. The disinfectant manufacturer's directions should be followed properly for optimum results. Water-based disinfectant solutions are preferred.

**LOT NUMBER AND EXPIRATION DATE**

1. Do not use after expiration date. ISO standard uses: "YYYY/MM."
2. The following numbers should be quoted in all correspondences:
  - Reorder Number
  - Lot number
  - Expiration Date

<sup>1</sup>Use suitable visible light curing unit designed to cure materials containing camphorquinone (CQ) initiator, i.e. spectral output containing 470 nm. Minimum light output must be at least 550mW/cm<sup>2</sup> exposure. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations.

*Manufactured in the U.S.A by:*  
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