**FluroShield®
Visible Light Cure Pit & Fissure Sealant**

**DIRECTIONS FOR USE – ENGLISH**

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

FluroShield® VLC Pit & Fissure Sealant is a sealant containing 50% by weight of inorganic filler having releasable fluoride, designed to seal pits and fissures. The use of FluroShield® Sealant is intended to be a fluoride supplement, and as such, there is no need to alter the normal fluoride regimen of the patient. In vitro data indicates that the protective action of the sealant is primarily at the enamel/sealant interface.

FluroShield® Sealant is designed for use directly following phosphoric acid conditioning.

1. FluroShield® VLC Pit & Fissure Sealant is intended for use on intact, uncontaminated, phosphoric-acid conditioned enamel. Buccal and lingual grooves should only be treated when the grooves are fully clear of gingival contact. If a carious lesion is detectable, a sealant should not be used.

2. W ear suitable protective clothing, eyew ear, and gloves.

3. C ontact with saliva, blood or other contam inate during placem ent may cause failure of the sealant. U se of FluroShield® Sealant is intended to be a fluoride supplem ent, and as such, there is no need to alter the normal fluoride regimen of the patient. In vitro data indicates that the protective action of the sealant is primarily at the enamel/sealant interface.

4. C ontact with saliva, blood or other contam inate during placem ent may cause failure of the sealant.

5. T he FluroShield® Sealant container should be tightly closed im m ediately after use. N OTE: FluroShield® Sealant teeth are filled by weight. Air is included in each tube to ensure stability. Tubes should be allowed to refill w ith air after dispensing before closing.

6. U se only in w ell ventilated areas.

7. A llow F luroShield ® Sealant m aterial to reach room  tem perature prior to use for optim um  flow.

8. If evidence of separation is noted, gently knead the tube until the m aterial is uniform  in appearance.

**INDICATIONS FOR USE**

Preventive sealing of pits and fissures in the primary and secondary dentition in combination with the acid-etch technique.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

1. FluroShield® Sealant contains polym erizable methacrylates. Avoid prolonged or repeated exposure with skin, oral soft tissues, and eyes. Irritation and possible corneal damage may result. Skin rash, oral mucosa irritation, or other allergic reactions (allergic contact dermatitis) may result in susceptible individuals. Do not take internally.

2. Eye Contact: Before using this product, wear protective glasses as well as covering the patient’s eyes. In case of eye contact, flush w ith flowing water for 15 minutes and seek medical attention.

3. Skin Contact: Avoid prolonged or repeated exposure to skin. If contact with skin occurs immediately wipe off thoroughly w ith cotton and alcohol and then wash thoroughly w ith soap and water. If skin rash or sensitization or other allergic reaction occurs, discontinue use and seek medical attention.

4. Oral mucosa contact: Avoid contact w ith oral soft tissues. If accidental contact occurs, rinse w eil w ith w ater and then expectorate. Contact of the material may cause soft tissue irritation. This is most often a temporary phenomenon and should disappear within one day. If the condition persists, seek medical attention.

5. Buccal and lingual grooves should only be treated when the grooves are fully clear of gingival contact. If a carious lesion is detectable, a sealant should not be used.

**COMPOSITION**

Urethane Bis-GMA; Dimethacrylate resins; Barium aluminoborosilicate glass; Sodium Fluoride; Photoinitiator; Photoaccelerators; Silicon Oxide

**ADVERSE REACTIONS**

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 W arnings)

**INTERACTIONS**

Eugenol-containing dental materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.

**STEP-BY-STEP DIRECTIONS FOR USE**

1. C leaning

   Clean uninstrumented enamel of occlusal surface, including pits and fissures with a rubber cup and pumice or a cleaning paste such as Nupro® Prophylaxis Paste. Wash thoroughly w ith water spray and air dry.

2. I solation

   Isolate teeth to be sealed using cotton rolls or rubber dam . Dry teeth w ith oil-free compressed air.

3. T ooth Conditioning

   3.1 Apply Caulk® 50% Tooth Conditioner Liquid (see manufacturer’s complete Directions For Use prior to use) using a saturated cotton pellet - 60 seconds for permanent teeth; 90 seconds for deciduous teeth. Use a continuous, gentle wiping motion. Avoid pressure. Use additional conditioning solution to maintain a wet surface. For buccal and lingual pits and grooves, condition at least 2-3mm of surrounding enamel. (See F ig. 1)

   3.2 Rinse teeth w ith air-water spray. Remove water by suction. Re-etch for 10 seconds if salivary contamination occurs, then thoroughly wash and dry w ith oil-free compressed air. Entire surface should have a dull frosted appearance; otherwise, re-etch required areas. Take care not to contaminate etched surfaces.

4. P lacement

   4.1 Dispense F luroShield® Sealant material on a paper mix pad. Cover to avoid exposure to operatory light if not used immediately. Replace container cap.

   4.2 Pick up a liberal amount of sealant material using disposable brush provided. (See F ig. 2) Apply sealant material along length of fissure. (See F ig. 3) Do not try to force sealant material into fissure orifice w ith bristle tips as this could create voids. Sealant should extend midw ay up the inclined planes to just clear occlusion. (See F ig. 4) Featheredge sealant to enamel border w ith a gentle lapping motion. (See F ig. 5 and F ig. 6 for correct amount of sealant material to be used.)

5. C uring

   Light cure all coated surfaces, keeping end of light tip about 1-2mm from the surface, with a suitable visible light curing unit designed to cure materials containing camphorquinone (CQ) initiator, i.e. spectral output containing 470nm. Minimum light output must be at least 550mW/cm² exposure for at least 20 seconds. (See F ig. 7) Refer to curing light manufacturer’s recommendations for compatibility and curing recommendations. Move the tip slowly across the surface so that all surfaces are exposed equally and increase time proportionately.

6. F inishing

   Before removing the cotton rolls or rubber dam , examine the entire surface for completeness of cure and absence of voids. Apply a small amount of material as outlined above, including some overlap of the surrounding area as needed. N OTE: After curing, a thin, air-inhibited film w ill be present on the exposed surface of the material. Wipe the air-inhibited film off the surface of the cured sealant material w ith a damp cotton pellet and dry the cavity.

**STORAGE**

FluroShield® Sealant material containers should be stored w ith the original cap only, kept out of direct sunlight and stored in a well ventilated place at temperature not exceeding 25°C/77°F. R efrigerated storage is not required but is acceptable when not in use. Separation of solid and liquid phase of the composition is accelerated at elevated temperatures. Allow material to reach room temperature prior to use.

Protect from moisture. Do not freeze. Do not use after expiration date.
7. Adjust any occlusal interference with a light touch of a fine stone or by the use of Enhance® Finishing System. (See manufacturer’s complete Directions for Use) Slow speed may provide better control of adjustment. Additional polishing is not usually necessary.

**REAPPLICATION OF SEALANT**

Sealant should be examined every six months. If sealant is entirely missing, repeat the total procedure. If part of the sealant is present, test its attachment using a sharp instrument. Freshen any firmly bonded sealant surface with a fine stone or medium grade pumice. Condition the entire occlusal surface, rinse and thoroughly air dry and apply new sealant as outlined above.

**CLEANING AND DISINFECTION INSTRUCTIONS**

Tubes and caps may be cleaned by scrubbing with hot water and soap or detergent. Tubes should be wiped, not immersed. Tubes exposed to spatter or spray of body fluids, or touched by contaminated hands or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are those that are EPA registered as tuberculocidal. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide and dual or synergized quaternary ammoniums are approved disinfectants. Do not immerse tubes in disinfectant. Disinfect the tubes by spraying or wiping. 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 degrade the tubes and caps. 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 on package
   - Expiration date