

FluroShield®

Visible Light Cure Pit & Fissure Sealant

DENTSPLY
CAULK

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 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.

FluroShield® Sealant is intended to be used following application of Caulk® 50% Tooth Conditioner Liquid. Use with other enamel conditioners, or in conjunction with self-etch or conventional etch adhesives is at the discretion and sole responsibility of the practitioner.

COMPOSITION

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

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 polymerizable 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.
Eye Contact: Before using this product, wear protective glasses as well as covering the patient's eyes. In case of eye contact, flush with flowing water for 15 minutes and seek medical attention.
Skin Contact: Avoid prolonged or repeated exposure to skin. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash thoroughly with soap and water. If skin rash or 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, rinse well with water 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.
2. FluroShield® Sealant is designed for use directly following phosphoric acid conditioning (etching) of enamel. Phosphoric acid is corrosive and may be hazardous. Refer to phosphoric acid conditioner manufacturer's complete *Directions for Use* before use.

PRECAUTIONS

1. This product is intended to be used 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. Wear suitable protective clothing, eyewear, and gloves.
3. Contact with saliva, blood or other contaminate during placement may cause failure of the sealant. Use of a rubber dam or adequate isolation is recommended.
4. FluroShield® Sealant is a visible light-cured material. Proceed immediately once material has been placed on mixing pad or protect from ambient light.
5. The FluroShield® Sealant container should be tightly closed immediately after use. **NOTE:** FluroShield® Sealant tubes are filled by weight. Air is included in each tube to ensure stability. Tubes should be allowed to refill with air after dispensing before closing.
6. Use only in well ventilated areas.
7. Allow FluroShield® Sealant material to reach room temperature prior to use for optimum flow.
8. If evidence of separation is noted, gently knead the tube until the material is uniform in appearance.

STORAGE

FluroShield® Sealant material containers should be stored with the original cap only, kept out of direct sunlight and stored in a well ventilated place at temperature not exceeding 25°C/77°F. Refrigerated 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.

ADVERSE REACTIONS

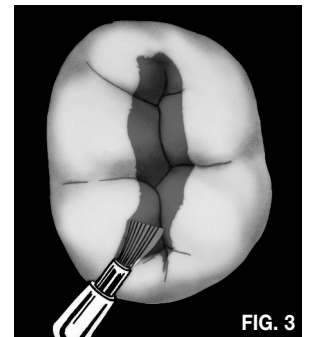
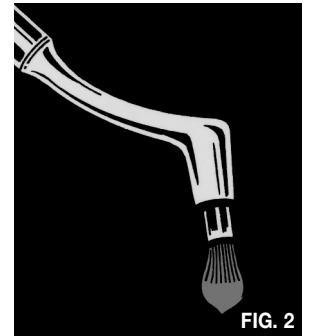
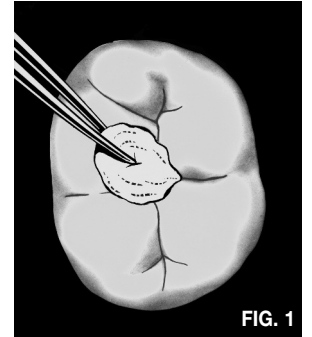
Product may irritate the eyes and skin. **Eye contact:** irritation and possible corneal damage. **Skin contact:** irritation or possible allergic response. Reddish rashes may be seen on the skin. **Mucous Membranes:** inflammation, edema, sloughing. (See *Warnings*)

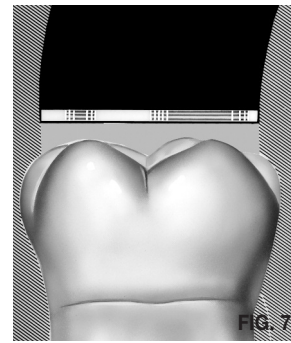
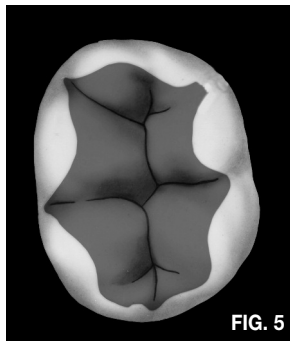
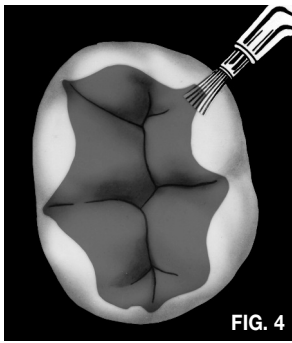
INTERACTIONS

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. **Cleaning**
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 with water spray and air dry.
2. **Isolation**
Isolate teeth to be sealed using cotton rolls or rubber dam. Dry teeth with oil-free compressed air.
3. **Tooth 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 *Fig. 1*)
 - 3.2 Rinse teeth with air-water spray. Remove water by suction. Re-etch for 10 seconds if salivary contamination occurs, then thoroughly wash and dry with 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. **Placement**
 - 4.1 Dispense FluroShield® Sealant material on a paper mix pad. Cover to avoid exposure to operator light if not used immediately. Replace container cap.
 - 4.2 Pick up a liberal amount of sealant material using disposable brush provided. (See *Fig. 2*) Apply sealant material along length of fissure. (See *Fig. 3*) Do not try to force sealant material into fissure orifice with bristle tips as this could create voids. Sealant should extend midway up the inclined planes to just clear occlusion. (See *Fig. 4*) Featheredge sealant to enamel border using a gentle lapping motion. (See *Fig. 5* and *Fig. 6* for correct amount of sealant material to be used.)
5. **Curing**
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 *Fig. 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. **Finishing**
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. **NOTE:** After curing, a thin, air-inhibited film will be present on the exposed surface of the material. Wipe the air-inhibited film off the surface of the cured sealant material with a damp cotton pellet and dry the cavity





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

Manufactured in the U.S.A. by:
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