

3M ESPE

Clinpro™ Sealant

ENGLISH

GENERAL INFORMATION

3M™ ESPE™ Clinpro™ Sealant is a light-cure, fluoride releasing pit and fissure sealant with a unique color-change feature. Clinpro Sealant is pink when applied to the tooth surface, and changes to an opaque off-white color when exposed to light. The pink color aids the dental professional in the accuracy and amount of material placed during the sealant procedure. When light-cured, the pink sealant will transform to an opaque off-white color.

Note: The change of color from pink to opaque off-white is not a cure indicator. Sealant needs to be cured with a dental curing light for the recommended exposure time. A sealant exhibiting any pink coloring is not completely cured.

- Meets ISO 6874 (Dentistry - Polymer-based pit and fissure sealants)
- BIS-GMA / TEGDMA resin composition
- Unfilled
- Curing light must have minimum output of 400 mW/cm²
- Use at room temperature

INDICATION

Sealing the enamel pits and fissures of teeth to aid in the prevention of caries.

PRECAUTIONARY INFORMATION FOR PATIENTS

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

PRECAUTIONARY INFORMATION FOR DENTAL PERSONNEL

Etchant Precautions

3M™ ESPE™ Scotchbond™ Universal Etchant contains 32% by weight phosphoric acid. Protective eyewear for patients and dental staff is recommended when using etchants. Avoid contact with oral soft tissue, eyes, and skin. If accidental contact occurs, flush immediately with large amounts of water. For eye contact, immediately rinse with plenty of water and seek medical attention.

Sealant Precautions

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

3M ESPE MSDS information can be obtained from www.3MESPE.com or contact your local subsidiary.

INSTRUCTIONS FOR USE

Preparation: Follow the directions corresponding to the dispensing system chosen. Sealant is light-sensitive. Exposure to overhead operatory lights will initiate the color change and curing.

Syringe

1. Protective eyewear is recommended for patients and staff when using a syringe type dispenser.
2. Prepare delivery system: Remove cap from syringe and SAVE. Twist a disposable dispensing tip securely onto the syringe. Holding the tip away from the patient and any dental staff express a small amount of material onto a mix pad or 2x2 gauze to assure the delivery system is not clogged. If clogged, remove the tip and express a small amount of material from the syringe. Remove any visible plug, if present, from the syringe opening. Replace dispensing tip and again check flow from tip. If clog remains, discard dispensing tip and replace with a new one.
3. At the completion of the procedure, remove used dispensing tip and discard. Twist on storage cap. Storage of the syringe with a used dispensing tip, or without the storage cap, will allow drying or curing of the product and consequent clogging of the system. Replace storage cap with a new dispensing tip at next use.

Bottle

1. Dispense 1 to 2 drops of sealant into the mix well. Immediately slide cover over well to protect from light.
2. Re-cap sealant bottle.
3. After removing material from well, always replace cover slide.

Directions

The acid-etch technique requires care, particularly for isolation and prevention of contamination. The enamel to be bonded must be cleaned, and thoroughly washed and dried, and maintained free from contamination after etching procedure and prior to sealant placement. As an alternative to the acid-etch technique the use of 3M™ ESPE™ Adper™ Prompt™ Self-Etch Adhesive may be substituted. Follow the Adper Prompt Adhesive instructions, section titled: Instructions for bonding light-cured dental sealants. If Adper Prompt Adhesive is used, enamel must still be thoroughly cleaned and isolated; follow instructions 1-4 in the acid-etch technique.

Acid-etch technique

1. **Check air/water syringe.** Blow a jet of air from syringe onto a glove or mirror. If small droplets are seen the syringe must be adjusted so only air is expressed. Any moisture contamination during certain stages of this procedure will compromise the integrity of a sealant.

2. **Select Teeth.** Teeth must be sufficiently erupted so that a dry field can be maintained. The morphology of the pits and fissures should be deep.

3. **Clean Enamel.** Thoroughly clean teeth to remove plaque and debris from enamel surfaces and fissures. Rinse thoroughly with water.

Note: Do not use any cleaning medium that may contain oils. If cleaning teeth using an air-polisher that utilizes sodium bicarbonate, it is recommended to repeat steps 5 and 6, or apply hydrogen peroxide to the surface for 10 seconds to neutralize the sodium bicarbonate, then rinse thoroughly with water.

4. **Isolate Teeth and Dry.** While a rubber dam provides the best isolation, cotton rolls used in conjunction with isolation shields are acceptable. Use saliva ejection device or high volume evacuation if possible.

5. **Etch Enamel.** Apply a generous amount of etchant to all enamel surfaces to be sealed, extending beyond the anticipated margin of the sealant. Etch for a minimum of 15 seconds, but no longer than 60 seconds.

6. **Rinse Etched Enamel.** Thoroughly rinse teeth with air/water spray to remove etchant. Remove rinse water with suction. Do not allow patient to swallow or rinse. If saliva contacts the etched surfaces, re-etch for 5 seconds and rinse.

7. **Dry Etched Enamel.** Thoroughly dry the etched surfaces. Air should be oil and water free. The dry etched surfaces should appear as a matte frosty white. If not, repeat steps 5 and 6. **DO NOT ALLOW THE ETCHED SURFACE TO BE CONTAMINATED.** Clinical studies have clearly shown that moisture contamination of these surfaces is the main cause for failure of pit and fissure sealants. Immediately apply sealant.

8. **Apply Sealant.** Using the syringe needle tip or a brush, slowly introduce sealant into the pits and fissures. Do not let sealant flow beyond the etched surfaces. Stirring the sealant with the syringe-tip during or after placement will help eliminate any possible bubbles, and enhance the flow into the pit and fissures. An explorer may also be used.

Cure the sealant by exposing it to light from a 3M ESPE light curing unit, or other curing unit of comparable intensity. A 20-second exposure is needed for each surface. The tip of the light should be held as closely as possible to the sealant, without actually touching the sealant. When set, the sealant forms a hard, opaque film, off-white in color with a slight surface inhibition.

9. **Evaluate Sealant.** Inspect sealant for complete coverage and voids. If surface has not been contaminated, additional sealant may be added. If contamination has occurred re-etch, rinse, and dry prior to placing more sealant.

10. **Dismissal.** Wipe the sealant with a cotton applicator to remove the thin sticky film on the surface. Check occlusion and adjust as required.

STORAGE AND USE

- Replace caps on syringes and bottles immediately after use.
- Do not expose materials to elevated temperature.
- Do not store materials in proximity to eugenol-containing products.

This product is designed to be stored and used at room temperature. Shelf life at room temperature is 24 months. Ambient temperatures routinely higher than 27°C/80°F, or lower than 10°C/50°F, may reduce shelf life. See outer package for expiration date.

Disinfect this product using an intermediate level disinfection process (liquid contact) as recommended by the Centers for Disease Control and endorsed by the American Dental Association. Guidelines for Infection Control in Dental Health-Care Settings – *MMWR*, December 19, 2003:52(RR-17), Centers for Disease Control and Prevention.

DISPOSAL

See the Material Safety Data Sheet (available at www.3MESPE.com or through your local subsidiary) for disposal information.

CUSTOMER INFORMATION

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Caution: U.S. Federal law restricts this device to sale by or on the order of a dental professional.

WARRANTY

3M ESPE warrants this product will be free from defects in material and manufacture. **3M ESPE 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 product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

LIMITATION OF LIABILITY

Except where prohibited by law, 3M ESPE 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.

3M ESPE Customer Care/MSDS Information:
U.S.A. 1-800-634-2249 and Canada 1-888-363-3685.



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