

XENO® IV

One Component Light Cured Self-Etching Dental Adhesive

DIRECTIONS FOR USE - ENGLISH

XENO® IV One Component Light Cured Self-Etching Dental Adhesive is a one-component light cured self-etching and self-priming dental adhesive designed to bond composite and compomer materials to enamel and dentin. XENO® IV One Component Light Cured Self-Etching Dental Adhesive combines etchant, primer and adhesive in a single bottle. The reduction of components and treatment steps simplifies use, maintaining superior bond strengths and protection against microleakage.

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

COMPOSITION

Mono-, Di- and Trimethacrylate resins
PENTA (dipentaerythritol penta acrylate monophosphate)
Photoinitiators
Stabilizers
Cetylamine hydrofluoride
Acetone
Water

INDICATION

Adhesive for direct, light-cured composite and compomer restorations.

CONTRAINDICATIONS

1. XENO® IV Adhesive is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.
2. XENO® IV Adhesive is contraindicated for direct application to dental pulp tissue (direct pulp capping).
3. XENO® IV Adhesive is contraindicated for use in conjunction with or following application of phosphoric acid tooth conditioners.

WARNINGS

1. XENO® IV Adhesive is acidic in nature and contains polymerizable acrylate and 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: XENO® IV Adhesive 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 splashing material. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.

Skin contact: XENO® IV Adhesive is acidic and contains polymerizable monomers which can cause skin irritation or 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. XENO® IV Adhesive contains acetone. Do not breathe vapor. **Inhalation:** Give oxygen or artificial respiration if necessary.

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. Wear suitable protective eyewear, clothing and gloves. Protective eyewear is recommended for patients.
3. 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.
4. XENO® IV Adhesive is less effective on unground, unprepared, or uncut enamel. Overfilling of the restorative onto unground, or uncut enamel could cause marginal discoloration. For optimal bonding results, the enamel in Class III, IV, V's and Diastema Closures should be beveled before treatment with the XENO® IV Adhesive.
5. Insufficient data exist to support the use with cementation of indirect restorations, with self-cure materials, or with dual-cure materials without sufficient light curing. Chemical/Product incompatibility may adversely affect product efficacy, leading to premature restoration failure.
6. Insufficient data exist to support the use of desensitizing agents and/or cavity cleansing agents with XENO® IV Adhesive. Recommended pre-treatment is pumice or prophylaxis paste with a rubber cup (*see Step-by-Step Instructions*).
7. The XENO® IV Adhesive bottle should be tightly closed immediately after use.
8. XENO® IV Adhesive is light-cured material. Proceed immediately once material has been placed in mixing well or protect from ambient light. The components are cured by visible light.
9. Use only in well ventilated areas.
10. Flammable: XENO® IV Adhesive contains acetone. Keep away from sources of ignition.
11. Single dose containers are intended for single use only, and should be discarded after use. Do not re-seal or re-use.
12. **Storage and Shelf Life:** XENO® IV Adhesive 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, skin and mucous membranes. **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 FOR USE - LIGHT CURED DIRECT RESTORATION (LIGHT CURED COMPOSITE RESIN AND COMPOMERS)

1. Cleaning

For optimal adhesion, always instrument (bevel) all enamel and/or margins (carbide or diamond bur) prior to application. Clean freshly instrumented enamel and dentin with water spray and then air dry. Clean uninstrumented dentin with a rubber cup and pumice or a cleaning paste such as Nupro® Prophylaxis Paste. Wash thoroughly with water spray and blot or lightly air dry. Do not desiccate dentin.

2. Pulp Protection

For direct and indirect pulp capping, cover the dentin close to the pulp (less than 1mm) with a hard setting calcium hydroxide liner (Dycal® Liner) leaving the rest of the cavity surface free for bonding with XENO® IV Adhesive.

Once the surfaces have been properly treated, **they must be kept uncontaminated**. If salivary contamination occurs, repeat procedure beginning at Step 1.

3. Application of XENO® IV Adhesive

3.1. Unit Dose Container: Grasp container at each end, or insert into holder, placing thumb along center score. Firmly apply pressure until container separates. Holder may be placed on the tabletop or held between fingers for convenience. Insert disposable applicator into opening to saturate applicator tip.

Conventional Bottle: Place 2-3 drops of XENO® IV Adhesive into a clean well. Replace cap promptly.

3.2 Using the disposable microbrush applicator tip supplied, immediately apply and scrub surfaces with generous amounts of XENO® IV Adhesive to thoroughly wet all the tooth surfaces for 15 seconds. For larger restorations, i.e. MOD in molars, a scrubbing time of 20 seconds is recommended.

3.3 Apply a second application of XENO® IV Adhesive with the microbrush as above, scrubbing for 15 seconds (20 seconds for larger restorations).

3.4 Remove excess solvent by gently drying with clean, dry air from a dental syringe for at least 5 seconds. Surface should have a uniform glossy appearance. If not, repeat application and air dry.

3.5 Cure XENO® IV Adhesive for 10 seconds¹ using a curing light. Proceed immediately to completion/restorative material placement.

4. Completion

Place restorative material over the cured XENO® IV Adhesive as per restorative material manufacturer's directions.

CLEANING AND DISINFECTION

To prevent XENO® IV Adhesive bottle from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended to avoid package contamination. Repeated disinfection may damage label. Do not attempt to clean, disinfect or re-use applicator brush or unit dose container. Properly dispose used brushes and containers.

LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard is used: "YYYY/MM"

2. The following numbers should be quoted in all correspondence:

- Reorder Number
- Lot number on bottle/unit dose
- Expiration date on bottle/unit dose

¹ Check curing light for minimum curing output of at least 300 mw/cm² and a spectral output including 470nm (peak absorption of the CQ photoinitiator).

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