

DENSPLY
CAULK

Esthet·X[®]flow

liquid micro hybrid

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DIRECTIONS FOR USE

DIRECTIONS FOR USE - ENGLISH

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

Esthet•X®flow liquid micro hybrid restorative is a composite resin restorative material with flow characteristics that make it ideal for small cavities in anterior and posterior teeth. Esthet•X®flow restorative adapts to the cavity wall without the use of hand instruments. The unique “stackable” flow characteristics allow intimate adaptation without slumping. Esthet•X®flow is a hybrid composite possessing the high strength and wear resistance required by posterior and certain anterior restorations, combined with an easily achieved high surface luster and smoothness.

Esthet•X®flow restorative is used following application of ProBOND® All purpose Bonding Agent, Prime&Bond® NT™ Universal Dental Adhesive System, XENO® III Self Etch Adhesive or Xeno® IV One Component Light Cured Self Etch Adhesive. Use of other dentin/enamel adhesive systems with Esthet•X®flow restorative material is at the discretion and sole responsibility of the dental practitioner.

This one-component, visible light cured composite restorative is packaged in predosed Compula™ tips and syringes in 7 Vita®¹, 2 custom body and 1 opaque characterization shade for a total of 10 shades. Shade matching has been optimized to the Vita® System.

A1	B1
A2	C4
A3	U/LYG
A3.5	A2-opaque
A4	Bleach

¹Vita® is a registered trademark of Vita-Zahnfabrik H. Rauter GmbH & Co.

COMPOSITION

The resin matrix of Esthet•X®flow restorative consists of a urethane modified BisGMA-adduct, BisGMA and diluents.

Camphorquinone (CQ) Photoinitiator

Stabilizer

Pigments

The filler matrix of Esthet•X®flow restorative consists of barium fluoro alumino-boro silicate glass with a mean particle size of approximately 1µm and nanofiller silica (particle size <0.02µm).

INDICATIONS FOR USE

Esthet•X®flow liquid micro hybrid restorative is indicated for the following procedures:

1. Class V restorations
2. Conservative Class III restorations
3. Conservative Class I restorations
4. As a liner under direct restorative materials and under inlay restorations – Class II box liner

CONTRAINDICATIONS

Esthet•X®flow liquid micro hybrid restorative material is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

WARNINGS

1. Esthet•X®flow restorative 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: Esthet•X®flow restorative 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: Esthet•X®flow restorative 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 immediately.

2. When using a Compules® Tips Gun, dental professionals and patients should wear protective eyewear.
3. Esthet•X®flow restorative in Compula™ tips and syringes 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 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. Esthet•X®flow restorative should extrude easily. **DO NOT USE EXCESSIVE FORCE.** Excessive pressure may result in unanticipated extrusion of the material or cause the Compula™ tip to eject from the Compules® Tips Gun.
5. The Esthet•X®flow restorative material syringe should be tightly closed immediately after use. Do not allow dispensing tip to remain as a syringe cap. Replace original cap tightly after each use. Discard and properly dispose dispensing tips after use, as the tips may clog if material is allowed to dry or set inside.
6. Eugenol-containing dental materials should not be used in conjunction with Esthet•X®flow restorative because they may interfere with the hardening and cause softening of the polymeric components.
7. The Esthet•X®flow restorative is light-cured material. Proceed immediately once material has been placed. Protect from ambient light.
8. Compula™ tips are designed for one time use. Discard after use. Do not reuse.
9. DENTSPLY Caulk supplies the appropriate dispensing tip for the Esthet•X®flow restorative material syringe. This tip is the only tip that should be utilized for placement of the material.
10. Use of Compula™ tips with the DENTSPLY Caulk Compules® Tips Gun is recommended. Use with another manufacturer's dispensing device is at the discretion and sole responsibility of the practitioner. Prior to use, consult the respective manufacturer's instructions for compatibility, use and sterilization information.
11. Insufficient data exist to support the use in Class I cavities with isthmus widths beyond central groove areas, or when replacing a functional cusp. Excessive wear or restoration failure may result.

12. **Storage:** Esthet•X®flow restorative Compula™ tips are for single use and should be discarded after use. Store syringe with original cap only. Keep out of sunlight. To be stored in a well ventilated place at temperatures between 10°C/50°F and 24°C/75°F. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date. The DENTSPLY Caulk Compules® Tips Gun should be sterilized by following the instructions in the *Sterilization and Maintenance of Compules® Tips Gun* section. The Compules® Tips Gun has an expected useful-life of one year from date of purchase.

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*

STEP-BY-STEP INSTRUCTIONS FOR USE

Direct Restoration, Class I, III, V

1. Shade Selection

Shade selection should be made prior to the restorative procedure while the teeth are hydrated. Remove any extraneous plaque or surface stain. A Vita® Lumin® Vacuum shade guide may be used. The Esthet•X®flow restorative shade corresponds to the central part of the respective Vita® tooth.

2. Cavity Preparation

Cavity design should be a minimal extension preparation with round internal line and point angles. Refinement of the cavo-surface margin (beveling) for enhancement of acid etching and enamel bonding is recommended. Unless repairing an otherwise sound restoration, intended to remain in place, no residual amalgam or other base material should be left in the internal forms of the preparation which would interfere with light transmission and the hardening of the restorative.

3. Placement of Matrix

The use of a Mylar, Bimatrix, sectional (e.g. Palodent® Sectional Matrix System) or thin matrix band (e.g. AutoMatrix® Retainerless Matrix System) and subsequent burnishing of the matrix band will improve final interproximal contact and contour. PRE-WEDGING/BiTine® RING PLACEMENT IS ADVOCATED TO ACHIEVE SLIGHT SEPARATION AND FACILITATE ACCEPTABLE PROXIMAL CONTACT.

4. **Pulp protection, Tooth Conditioning/Dentin Pretreatment, Adhesive Application**

Refer to adhesive 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 Esthet•X®flow restorative material.

5. Dispensing Esthet•X®flow restorative material

5.1 Syringes

- 5.1.1 Remove cap from the end of the syringe. To assure free flow of material from syringe, express a small amount onto pad, away from the patient field.
- 5.1.2 Attach disposable, gray dispensing tip to end of the syringe. Turn tip clockwise 1/4 to 1/2 turn to assure that it is fully seated. Tug on tip to be sure that it is locked into the collar of the syringe.
- 5.1.3 Esthet•X®flow restorative should flow freely with gentle pressure. **DO NOT USE EXCESSIVE FORCE.** If more than gentle pressure is required, remove from patient field and check for obstruction.
- 5.1.4 **DISCARD AND PROPERLY DISPOSE DISPENSING TIP IMMEDIATELY AFTER USE. REPLACE ORIGINAL CAP.** Do not store syringe with gray dispensing tip in place. **STORE ONLY WITH ORIGINAL CAP.**
NOTE: It is recommended to pull back slightly on the syringe plunger after use to prevent excessive flow of material.

5.2 Compula™ Tips

- 5.2.1 The pre-dosed Compula™ tip provides the combination of a unit dose Compules® tip with a metal cannula applicator tip.
- 5.2.2 Load Compules® Tips Gun with pre-dosed Compula™ tip. Insert Compula™ tip into the notched opening of the Compules® Tips Gun barrel. Be certain that the collar on the Compula™ tip is inserted first.
- 5.2.3 Remove the colored cap from the Compula™ tip. The Compula™ tip may be rotated 360° to gain the proper angle of entrance into the cavity.
- 5.2.4 Dispense the material into the cavity preparation using a slow, steady pressure. **DO NOT USE EXCESSIVE FORCE.**
- 5.2.5 To remove the used Compula™ tip, be sure that the Compules® Tips Gun plunger is pulled back completely by allowing the handle to open to its widest position. Apply a downward motion to the front end of the Compula™ tip and remove.

6. Placement of Esthet•X®flow restorative material

Dispense Esthet•X®flow restorative directly into preparation site/tooth surface from the Compula™ tip or syringe tip using slow, steady pressure. Avoid lifting the tip while dispensing to minimize air entrapment. Any visible air bubbles should be pierced with a clean, sharp explorer prior to curing. Material may be placed and light cured in increments up to 2mm (see *Curing, Step 7*). In deeper preparations it is recommended to place material in 2mm increments, thoroughly light curing each increment. For maximum light transmission and to minimize finishing, avoid overfilling cavity.

7. Curing

Light cure each area of the restoration 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 300mW/cm² exposure for at least 20 seconds. For darker/opaque shades (A4, C4, A2-O) cure for another 20 seconds. Some advanced performance curing units (e.g. Smartlite® iQ™ L.E.D. Curing Light) have been shown to cure 2mm increments of most shades of Esthet•X®flow restorative in 10 seconds. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations. The Esthet•X®flow restorative should be additionally exposed to the curing unit through the proximal, lingual, and buccal enamel walls following matrix removal for the recommended time.

8. Finishing and Polishing

- 8.1 Begin finishing immediately after curing. Due to the “stackable” nature of Esthet•X®flow restorative, precise placement is possible, and should be observed, minimizing the need for gross finishing.
- 8.2 If necessary, gross excess may be removed with Prisma® Finishing Burs or other carbide or diamond finishing instruments. Preferably, finishing is recommended by the use of Enhance® Finishing System. See manufacturer's complete directions for use.
- 8.3 To achieve a very high luster on Esthet•X®flow restorative, it is necessary to complete the polishing. PoGo® One Step Diamond Micro-Polisher System and/or Prisma®•Gloss™ Composite Polishing Pastes are recommended. See manufacturer's complete directions for use.

STEP-BY-STEP INSTRUCTIONS FOR USE

Cavity Liner

Prior to use as a cavity liner, follow steps 1 through 5, outlined above for:

1. Shade selection
2. Cavity preparation

3. Matrix placement
4. Pulp protection, Tooth Conditioning/Dentin Pretreatment, Adhesive Application
5. Dispensing (syringe or Compula™ Tip)
6. **Placement**

Dispense Esthet•X®flow restorative directly into preparation site/surfaces. For most cavity lining applications, a thickness of 1mm or less is recommended. With the exception of Class II proximal box (gingival) margins, cavity margins/conditioned enamel are usually closed with selected restorative material. Lining is generally confined to internal conditioned dentin surfaces. Avoid lifting the tip while dispensing to minimize air entrapment. Any visible air bubbles should be pierced with a clean, sharp explorer prior to curing.

Technique Tip: Use of a clean instrument such as a sharp explorer may be used to evenly spread a thin layer of dispensed Esthet•X®flow restorative material over prepared cavity (dentin) surfaces prior to curing.

7. **Curing**

Light cure each area of the lined 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 300mW/cm² exposure for at least 40 seconds for liner application.

8. If a thickness of material greater than 1mm is desired, repeat placement step 6 and curing step 7, placing material in 1mm increments and curing, until desired thickness is reached.
9. Proceed immediately to complete the restoration per restorative material manufacturer's directions for use. For adhesive restorations, do not disturb or allow contamination of cured liner surface. If contamination occurs, follow adhesive manufacturer's directions for use for re-application of adhesive.

Technique Tip: If surfaces remain undisturbed, additional application of adhesive between increments is neither necessary nor recommended.

CLEANING AND DISINFECTION

To prevent Esthet•X®flow restorative syringes from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended to avoid syringe contamination. Repeated disinfection may damage label.

Do not attempt to clean, disinfect or re-use Compula™ tips. Properly dispose used Compula™ tips.

STERILIZATION AND MAINTENANCE OF COMPULES® TIPS GUN

1. To clean the Compules® Tips Gun, the following procedure is recommended. Partially close the syringe and place thumb under the rear portion of the hinge.
2. Push upward and lift hinge separating the Compules® Tips Gun, exposing the plunger. If the plunger has excess material build-up, clean with an alcohol moistened gauze. The Compules® Tips Gun may be cleaned by scrubbing with hot water and soap or detergent. It is not recommended to submerge Compules® Tips Gun into disinfecting solutions.
3. The Compules® Tips Gun may be autoclaved. **NOTE:** As with any plastic instrument, the Compules® Tips Gun may weaken over time.
4. To reassemble, insert plunger into Compules® Tips Gun barrel, press components together and snap hinge mechanism in place. Prior to each use, check to make sure that the Compules® Tips Gun is fully engaged and in good working order.

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 correspondences:
 - Reorder number
 - Lot number on the syringe or Compula™ Tip
 - Expiration date on the syringe or Compula™ Tip

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