



DENTSPLY

Esthet•X[®]flow

liquid micro hybrid

CE
0120

Directions For Use



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Esthet•X[®]flow

liquid micro hybrid restorative

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 Prime&Bond[®] NT™, a universal self-priming dental adhesive designed to bond the restorative to enamel and dentin.

Composition:

Esthet•X[®]flow restorative

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

Prime&Bond[®] NT™

Di- and trimethacrylate resins

Nano-fillers (Amorphous Silicon Dioxide)

PENTA (dipentaerythritol penta acrylate monophosphate)

Photoinitiators

Stabilizers

Cetylamine hydrofluoride

Acetone

Caulk 34% Tooth Conditioner Gel:

Phosphoric Acid

Highly dispensed silicon dioxide

Colorant

Water

INDICATIONS FOR USE:

Esthet•X[®]flow flowable composite resin restorative is indicated for the following procedures:

1. Class V

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:

1. Esthet•X®flow liquid micro hybrid restorative and Prime&Bond® NT™ adhesive are contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.
2. Prime&Bond® NT™ adhesive is contraindicated for direct application to dental pulp tissue (direct pulp capping).
3. Caulk 34% Tooth Conditioner Gel is contraindicated for use on soft tissue including oral mucosa, skin, eyes and dental pulp tissue.

WARNINGS:

1. Esthet•X®flow restorative system contains polymerizable methacrylate monomers. Avoid prolonged or repeated contact with skin and eyes. Avoid prolonged inhalation. Do not take internally.
Eye & Skin Contact: Flush eyes with copious amounts of water for 15 minutes and seek medical attention. Wash skin thoroughly with soap and water after contact. If irritation persists, consult a physician. If skin sensitization or other allergic reaction occurs, discontinue use. Skin rash or other allergic reactions may result in susceptible individuals.
Inhalation: Move to fresh air. Give oxygen or artificial respiration as required.
Ingestion: Contact regional Poison Control Center immediately.
2. Prime&Bond® NT™ adhesive system contains polymerizable methacrylate monomers. Avoid prolonged or repeated contact with skin and eyes. Avoid prolonged inhalation. Do not take internally.
Eye & Skin Contact: Flush eyes with copious amounts of water for 15 minutes and seek medical attention. Wash skin thoroughly with soap and water after contact. If irritation persists, consult a physician. If skin sensitization or other allergic reaction occurs, discontinue use. Skin rash or other allergic reactions may result in susceptible individuals.
Inhalation: Move to fresh air. Give oxygen or artificial respiration as required.
Ingestion: Contact regional Poison Control Center immediately.
3. Prime&Bond® NT™ adhesive system contains acetone and is highly flammable. Do not breath vapors. Use only in well ventilated areas. Avoid prolonged inhalation. Avoid prolonged or repeated contact with skin and eyes. Do not take internally.
Inhalation: Move subject to fresh air. Give oxygen or artificial respiration as required.
Eye & Skin Contact: Flush eyes with copious amounts of water for at least 15 minutes and consult a physician. Wear suitable protective clothing and gloves. Wash skin with soap and water after contact and consult a physician if irritation persists.
Ingestion: Contact regional Poison Control Center immediately.
4. Caulk 34% Tooth Conditioner Gel contains phosphoric acid. Avoid contact with oral tissues, eyes and skin. Do not take internally.

Eye & Skin Contact: Flush eyes with copious amounts of water for 15 minutes and seek medical attention. Wash skin thoroughly with soap and water after contact. If irritation persists, consult a physician. If skin sensitization or other allergic reaction occurs, discontinue use. Skin rash or other allergic reactions may result in susceptible individuals.

Inhalation: Move to fresh air. Give oxygen or artificial respiration as required.

Ingestion: Contact regional Poison Control Center immediately.

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. Curing should be extended to 40 seconds for all shades when curing through tooth structure or when the distance from the curing light probe to the composite exceeds 3mm or if the halogen light output is $<300 \text{ mW/cm}^2$.
3. Esthet•X®flow restorative and Caulk 34% Tooth Conditioner Gel should extrude easily. DO NOT USE EXCESSIVE FORCE. Do not allow dispensing tip to remain as a syringe cap. Replace original cap tightly after each use to avoid evaporation. Discard and properly dispose dispensing tips after use, as the tips may clog if gel or material is allowed to dry or set inside.
4. 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.
5. Esthet•X®flow restorative and Prime&Bond® NT™ adhesive contain camphorquinone photoinitiator for visible light cure. Protect from exposure to ambient light. Containers should be tightly closed immediately after use.
6. Prime&Bond® NT™ adhesive is highly flammable. Dispose of in accordance with Federal, State and Local regulations. Keep away from heat, sparks and open flames. (See Warnings Statements)
7. Caulk 34% Tooth Conditioner Gel contains phosphoric acid. Dispose of in accordance with Federal, State and Local regulations. (See Warnings Statements)
8. **Storage and Shelf Life:** Store and use Esthet•X®flow restorative between 65°-80°F (18°-25°C). Keep Esthet•X®flow restorative and Prime&Bond® NT™ adhesive in a well-ventilated place. Do not use after expiration date. Refer to package of individual components for expiration dates.

ADVERSE REACTIONS:

1. Corneal damage may result with prolonged eye exposure to Prime&Bond® NT™ adhesive and Caulk 34% Tooth Conditioner Gel. (See Warnings Statements)
2. Allergic contact dermatitis and other allergic reactions may occur in susceptible individuals to Esthet•X®flow restorative, Prime&Bond® NT™ adhesive and Caulk 34% Tooth Conditioner Gel. (See Contraindications, Warnings and Precautions Statements)

STEP BY STEP INSTRUCTIONS FOR USE

Placement of Esthet•X®flow liquid micro hybrid restorative

1. Remove extraneous plaque and surface stain with a rubber cup and pumice or non-fluoridated prophylaxis paste.
 2. Select shade prior to the restorative procedure, while teeth are hydrated. A Vita® Lumin and/or an Esthet•X® shade guide may be used. The Esthet•X®flow corresponds to the middle/cervical 1/3 of the respective shade tab.
- *Vita® is a registered trademark of Vita-Zahnfabrik H. Rauter GmbH & Co.

Cavity Preparation

1. Cavity design should be a minimal extension preparation with round internal line and point angles.
2. Refinement of the cavo-surface margin for enhancement of acid-etching may be used if desired.
3. 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 the Prime&Bond® NT™ adhesive bond to tooth or with light transmission and the hardening of the restorative.
4. Clean un-instrumented enamel and dentin with a rubber cup and pumice or a non-fluoride cleaning paste such as Nupro® Prophylaxis Paste.
5. Wash thoroughly with water spray and air dry.
6. Clean freshly instrumented enamel and dentin with water spray and lightly air-dry or blot dry with a cotton pellet. **Avoid desiccating the dentin.**

Pulp Protection

In minimal depth cavity preparations, where remaining dentin thickness is judged to be greater than one mm, a calcium hydroxide base is not required. In all deep preparations, in close proximity to the pulp with less than one mm remaining dentin thickness, place a calcium hydroxide liner such as Dycal® or Prisma® VLC Dycal® Base/Liner Composition.

Tooth Conditioning

Tooth Conditioning is recommended for Esthet•X®flow.

Application of Caulk 34% Tooth Conditioner Gel

1. After application of rubber dam or other suitable isolation technique, apply Caulk 34% Tooth Conditioner Gel.
2. Attach disposable, blue dispensing tip to the end of syringe. The blue dispensing tip may be bent for easy access.
3. Gently extrude Caulk 34% Tooth Conditioner Gel (34% phosphoric acid) to the cavity surfaces starting at the enamel margins. For best results, condition enamel for at least 15 seconds and dentin for no more than 15 seconds.
4. Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 10 seconds or until gel is completely rinsed away.
5. Blot dry conditioned areas with a moist cotton pellet. For best results, saturate a cotton pellet and remove excess water from the pellet by blotting it on a gauze pad before using the pellet to blot the tooth. Proceed immediately to

application of Prime&Bond® NT™ adhesive.

Important Note:

The goal of blot drying is to provide the correct amount of "wetness" on the tooth surface. This allows removal of excess moisture without desiccating the dentin. Do not rub the tooth surface when blot drying. Dentin should be blotted until there is no pooling of water, leaving a moist, glistening surface.

Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, repeat tooth conditioning for 10 seconds.

Application of Prime&Bond® NT™ Nano-Technology Light Cured Dental Adhesive

1. Dispense Prime&Bond® NT™ adhesive directly onto a clean disposable brush provided or place 2-3 drops of Prime&Bond® NT™ adhesive into a clean well. Replace cap promptly. Alternatively, open a fresh Prime&Bond® NT™ patient dose container.

Note: Patient dose containers are intended for single use only, and should be discarded after use. Do not re-seal or re-use.

2. Using the disposable brush supplied, immediately apply generous amounts of Prime&Bond® NT™ adhesive to thoroughly wet all the tooth surfaces. This surface should remain fully wet for 20 seconds and may necessitate additional applications of Prime&Bond® NT™ adhesive.
3. Remove excess solvent by gently drying with clean, dry air from a dental syringe for a least 5 seconds. Surface should have a uniform glossy appearance. If not, repeat application and air dry.
4. Cure Prime&Bond® NT™ adhesive for 10 seconds.

Important Note: When using a high performance unit such as the curing lights manufactured by DENTSPLY, a curing time of 10 seconds is sufficient. For other curing lights with an output lower than 300 mW/cm², a curing time of 20 seconds should be observed.

Placement of Esthet•X®flow Restorative

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.
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.
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.
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. **For Class I, Class III and Class V restorations.** Dispense Esthet•X®flow restorative directly into preparation site/surfaces. Cure each increment for 20 seconds. In deeper preparations exceeding 3 mm it is recommended to place material in 2mm increments, thoroughly light curing each increment

for 40 seconds. For maximum light transmission and to minimize finishing, avoid overfilling cavity. Be sure to expose each area of the entire restoration to the curing light cycle. Additionally, the restorations should be cured through any remaining tooth structure for an additional 20 seconds.

Important Note: A curing unit with an output of at least 300 mW/cm² should be used.

- 6a. **For use as a liner in a cavity preparation.** Dispense Esthet•X®flow restorative directly into preparation site/surfaces. It is recommended to cure the liner application for 40 seconds.
- 6b. Proceed immediately to placement of restorative material per each material's directions for use (e.g., Esthet•X®, TPH® Spectrum®, SureFil™) without disturbing liner surface.

Important Note: A curing unit with an output of at least 300 mW/cm² should be used.

Finishing and Polishing

1. Begin finishing immediately after curing. Due to the "stackable" nature of Esthet•X®flow, precise placement is possible, and should be observed, minimizing the need for gross finishing.
2. If necessary, gross excess may be removed with Prisma® Finishing Burs or other carbide or fine diamond finishing burs. Preferably, finishing is obtained by use of Enhance® Discs, Cups or Points and interproximal strip.
3. After finishing, a high luster can be obtained by polishing with the PoGo™ polishing system or Prisma® Gloss™, followed by Prisma® Gloss™ Extra Fine on an Enhance® foam cup.

BATCH NUMBER AND EXPIRATION DATE

1. Do not use after expiration date.
2. The following numbers should be quoted in all correspondences.
 - Reorder number
 - Lot number on the cartridge
 - Expiration date

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