

Esthet•X[®]

micro matrix restorative

DIRECTIONS FOR USE - ENGLISH

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

Esthet•X[®] Micro Matrix Restorative is a visible light cured, radiopaque, composite restorative material for anterior and posterior restorations of primary and permanent teeth. It is to be used following the application of a suitable dentin/enamel adhesive and is compatible with all DENTSPLY adhesives designed for use with visible light cured composite restoratives (see complete *Directions for Use* of selected adhesive). Use of other dentin/enamel adhesive systems with Esthet•X[®] 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 Compules[®] Tips and 3gm Easy•Twist syringes. The regular body shades are optimized to match the Vita[®] system. Additional available body, opacious dentin and translucent enamel shades are available for esthetically demanding applications existing beyond the traditional Vita[®] System. A custom blended shade guide is available to guide the clinician in shade selection and blending technique.

Esthet•X[®] Restorative material may be used with separately available BisGMA-based tints and opaques at the discretion and responsibility of the dental practitioner for individual custom characterization of the ultimate esthetic direct-placement restoration.

AVAILABLE SHADES

Opacious Dentin	Regular Body		Translucent Enamel
White-O = W-O	White=W	B5/Dark Yellow	Clear Enamel=CE
A2-O	Extra Light=XL	C1	White Enamel=WE
A4-O	A1	C2	Yellow Enamel=YE
B2-O	A2	C3	Amber Enamel=AE
C1-O	A3	C4	Grey Enamel=GE
C4-O	A3.5	C5/Extra Grey-Brown	
D3-O	A4	D2	
	B1	D3	
	B2	Universal	
	B3		

COMPOSITION

The resin matrix of Esthet•X[®] Restorative material consists of a Bis-GMA adduct, a Bis-EMA adduct, and triethylene glycol dimethacrylate.
Camphorquinone (CQ) Photoinitiator
Stabilizer
Pigments

The filler combination consists of barium fluoro alumino boro silicate glass with a mean particle size below 1µm and nanofiller silica (particle size 0.04µm).

INDICATIONS

- Esthet•X[®] Restorative material is indicated as a direct restorative for all cavity classes in anterior and posterior teeth.
- Esthet•X[®] Restorative material is indicated as a direct esthetic veneering restorative material and cosmetic reshaping (e.g., diastema closure, incisal lengthening).
- Esthet•X[®] Restorative material is indicated for the indirect fabrication of inlays and onlays.

CONTRADICTIONS

Esthet•X[®] Restorative material is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

WARNINGS

- Esthet•X[®] Restorative material 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[®] Restorative material 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[®] Restorative material 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 if necessary.

- When using a Compules[®] Tips Gun, dental professionals and patients should wear protective eyewear.

PRECAUTIONS

- This product is intended to be used only as specifically outlined in these *Directions for Use*. Any use of this product inconsistent with the *Directions for Use* is at the discretion and is the sole responsibility of the practitioner.
- Contact with saliva and blood during composite placement may cause failure of the restoration. Use of rubber dam or adequate isolation is recommended.
- Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
- Eugenol-containing 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.
- The Esthet•X[®] Restorative material is a light-cured material. Proceed immediately once material has been placed on pad or protect from ambient light.
- Material should extrude easily from the Compules[®] Tip. Use a gentle, even motion when exerting pressure on the Compules[®] Tips Gun. DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material or cause the Compules[®] Tip to eject from the Compules[®] Tips Gun.
- Compules[®] Tips are designed for one time use. Discard after use. Do not reuse.
- The Esthet•X[®] Restorative material Easy•Twist syringe should be tightly closed immediately after use.
- Use of Compules[®] 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.
- Storage:** Esthet•X[®] Restorative material Compules[®] Tips are for single use and should be discarded after use. Keep out of sunlight. To be stored at temperatures between 10°C/50°F and 24°C/75°F. Refrigerated storage is not required, but is acceptable when not in use. Allow material to reach room temperature prior to use. Excessive humidity can adversely affect the properties of Esthet•X[®] Restorative material. Protect from moisture. Do not freeze. Do not use after expiration date. The TruMatch[®] Restorative material shade guide should be disinfected by following the instructions in the Cleaning and Disinfection of the TruMatch[®] Shade Guide section. The Compules[®] Tips Gun should be sterilized by following the instructions in the Sterilization and Maintenance of Compules[®] Tips Gun section. 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*.

TECHNIQUE TIPS

Esthet•X[®] Restorative material is a "sculptable," non-sticky, material that resists slumping and allows the operator to create precise anatomical form.

- When using Esthet•X[®] Restorative material, it is best not to "spread" the material, but to "push" or "sculpt" the material.
- It is recommended to dispense/extrude material from a Compules[®] Tip with a slow, steady force.
- Rapid and/or forceful extrusion of the material from a Compules[®] Tip may cause material to appear whitish and/or separated. Upon placement and manipulation, material will coalesce without compromise in strength or esthetics.

Esthet•X® Restorative material was developed to provide the highest surface luster in order to replicate natural enamel. To achieve maximum polish and maintenance it is highly recommended to fully complete the polish of Esthet•X® Restorative material by finishing the restoration with Enhance® Finishing System and polishing with the PoGo® One Step Diamond Micro-Polisher System and/or Prisma®Gloss™ Composite Polishing Pastes.

OPTIMIZING SHADE SELECTION

1. The opacity of Esthet•X® Restorative material Body Shades has been scientifically designed to allow the tooth structure enamel and dentin to blend together with the composite with a life-like translucent result. Additional Opaque and Enamel Shades allow replacement of each component of lost tooth structure. Layered opacities of material visually blend to form a restoration with natural vitality and translucence.
2. The final shade will ultimately result from an interaction of the thickness of the layer(s) of restorative composite and surrounding tooth structure (enamel and/or dentin). The intensity of the shade is related to the thickness or thinness of opacious, body and/or translucent shade layers of the Esthet•X® Restorative material used. Restoration shade approximation to the selected shade tab of the TruMatch® shade guide occurs with restorations allowing adequate thicknesses of each recipe component, e.g., Class IV, labial-lingual Class III, etc. For restorations less than 2mm total thickness, e.g., conservative cosmetic veneering, and/or where significant shade lightening is desired, placement of a liquid opaquer may provide a more desirable foundation for subsequent shade layering.
3. In all cases, the use of a mock-up is an excellent method for shade verification. The technique includes the use of the shades and opacities as prescribed by the selected TruMatch® shade tab in the appropriate thicknesses to approximate that of the final Esthet•X® Restorative material restoration. The materials are placed on the clean, hydrated **unetched** tooth in the area of the cavity or restoration on the tooth. Each layer is applied without etch or bonding agent, then cured thoroughly. Layering and/or altering shades in varying thickness will allow trial customization of the final shade. The dentist, patient and ancillary dental support personnel can co-jointly view the shade selection result. After viewing, the composite material can be removed by the use of a dental explorer or scaler.
4. Be aware of room and ambient light effects on shade selection; incandescent versus fluorescent lighting versus natural daylight (ideal light is northern exposure/outdoors/overcast).
5. Room accessories can influence shade selection as with colored walls/wallpaper reflection. Also, the patient dental napkin should be removed. Observe tooth shades for short periods of time, using a blue background to “neutralize” the effect of extended shade viewing comparisons. Viewing a blue background will have a relaxing effect on the viewing operator’s photo/color optic discrimination. Eyes should be rested. It is useful to have ancillary corroboration on shade selection by dental personnel as well as by the dental patient.

STEP-BY-STEP INSTRUCTIONS

DIRECT RESTORATION

1. **Shade Selection:** Before selecting the shade, teeth should be clean, hydrated and free of extrinsic material or stain. The TruMatch® shade guide included in the Introductory Kit and the Complete Organizer System has been created to simulate the result of layering specific shades. Select the shade tab that simulates best the final desired result. Following the recipe on the shade tabs will create the desired shade. Mixing layered shades and various thicknesses will allow customized shade adjustability. Please refer to the *Optimizing Shade Selection* section above. Additionally, use of the Technique Guide will detail the step-by-step procedure for accurate shade reproduction.
2. **Cavity Preparation**
 - 2.1 Anterior Restorations: Use conservative cavity preparations for all Class III, IV and Class V restorations. Refinement of the cavo-surface margin (beveling) for enhancement of acid-etching, enamel bonding, and finishing procedures is recommended.
Technique Tip: Esthetic masking of underlying intrinsic staining may require deeper preparation, allowing for adequate restorative material blending.
 - 2.2 Posterior Restorations: Cavity design requirements are essentially a conventional preparation with refinement of the cavo-surface margin for enhancement of acid etching. 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® Restorative material.
5. **Placement of Esthet•X® Micro Matrix Restorative Material**
 - 5.1 Easy•Twist Syringe: Remove the cap from the Easy•Twist syringe by using lateral force. It is easier to remove the cap in a “snap-off” rather than a “pull-off” motion. Dispense the necessary amount of Esthet•X® Restorative material from the Easy•Twist syringe onto the mix pad by turning the handle slowly in a clockwise direction. To prevent oozing of the material when dispensing is completed, point the front tip of the Easy•Twist syringe upwards and turn the handle counter-clockwise and recap the Easy•Twist syringe. **Technique Tip:** Protect dispensed Esthet•X® Restorative material from premature polymerization via ambient light while current increment is adapted and light cured.

- 5.2 Pre-dosed Compules® Tips: Load Compules® Tips Gun with predosed Compules® Tip. Insert a Compules® Tip into the notched opening of the Compules® Tips Gun barrel. Be certain that the collar on the Compules® Tip is inserted first. Remove the colored cap from the Compules® Tip. The Compules® Tip may be rotated 360° to gain the proper angle of entrance into the cavity. To dispense the material into a cavity preparation, use a slow, steady pressure. **Do not use excessive force.** To remove the used Compules® 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 Compules® Tip and remove.
- 5.3 Optional Flowable Liner: Placement of a compatible flowable liner such as Esthet•X® flow Flowable Restorative or Dyract®flow Flowable Compomer (available separately) prior to placement of Esthet•X® Restorative material is optional. If desired, follow manufacturer’s directions for use.
- 5.4 Anterior Placement: Dispense Esthet•X® Restorative material directly into the cavity preparation/tooth surface from the Compules® Tip using slow, steady pressure. Excessive force is not necessary. Alternatively, material may be expressed onto a clean pad from the Compules® Tip or Easy•Twist syringe and carried to the preparation with suitable placement instrument. Adapt, contour and shape with appropriate composite instruments. Material may be placed and light cured in increments up to 2mm. (See *Curing, Step 6*) **Technique Tip:** For esthetic blending of shades, shade layers may be individually cured to form a foundation for subsequent shade placement.
- 5.5 Posterior Placement: Dispense Esthet•X® Restorative material directly into the cavity preparation from the Compules® Tip using slow, steady pressure. Excessive force is not necessary. Alternatively, material may be expressed onto a clean pad from the Compules® Tip or Easy•Twist syringe and carried to the preparation with suitable placement instrument.
 - 5.5.1 Class I and V: Esthet•X® Restorative material may be placed and adapted in 2mm increments, light curing each increment. (See *Curing, Step 6*)
 - 5.5.2 Class II: Beginning in the proximal box, firmly adapt a 2mm increment of Esthet•X® Restorative material to cavity walls and stabilize matrix band by stepping a clean non-serrated condenser (plugger) from middle to edges, reducing incorporated air and eliminating voids. Light cure (see *Curing, Step 6*). The remainder of the preparation may be filled in up to 2mm increments, each followed by light cure (see *Curing, Step 6*). Prior to light curing, contour and shape the final increment with the operator’s choice of clean carving and burnishing instruments. **Technique Tips:** To minimize finishing time, contour marginal ridge first before occlusal anatomy. Carve margins and anatomy to final form. Esthet•X® Restorative material resists slumping, allowing carving of the majority of anatomical form prior to visible light curing.
6. **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 470 nm. Minimum light output must be at least 550mW/cm² exposure for at least 20 seconds. Some advanced performance curing units (e.g. SmartLite® iQ™ L.E.D. Curing Unit) have been shown to cure 2mm increments of most shades of Esthet•X® Restorative material in 10 seconds. Refer to curing light manufacturer’s recommendations for compatibility and curing recommendations. The Esthet•X® Restorative material should be additionally exposed to the curing unit through the proximal, lingual, and buccal enamel walls following matrix removal for the recommended time.
7. **Finishing and Polishing**
 - 7.1 Begin finishing immediately after curing. Gross excess may be removed and general outline form established with Prisma® Finishing Burs or other carbide or diamond finishing instruments. Additional finishing is recommended by the use of Enhance® Finishing System. See manufacturer’s complete directions for use.
 - 7.2 To achieve a very high luster on Esthet•X® Restorative material, 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. Once polished with PoGo® polisher and/or both Prisma®Gloss™ pastes, Esthet•X® Restorative material will maintain its high surface gloss due to its micro matrix technology.

STEP-BY-STEP INSTRUCTIONS

FABRICATION OF INDIRECT INLAY/ONLAY

1. **Shade Selection:** Final desired shade selection should be accomplished prior to tooth preparation. Before selecting the shade, teeth should be clean, hydrated and free of extrinsic material or stain. The TruMatch® shade guide included in the Introductory Kit and the Complete Organizer System has been created to simulate the result of layering specific shades. Select the shade tab that simulates best the final desired result. Following the recipe on the shade tabs will create the desired shade. Mixing layered shades and various thicknesses will allow customized shade adjustability. Please refer to the *Optimizing Shade Selection* section.
2. **Cavity Preparation:** Cavity design requirements are essentially a conventional preparation. Rounding of internal angles and refinement of the cavo-surface margin for enhancement of enamel bonding and finishing procedures is recommended. 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 luting cement. Refer to adhesive and/or luting cement manufacturer’s directions for base/liner/pulp protection requirements.
3. **Impression, Master Cast Fabrication**
 - 3.1 Make an accurate impression of the preparation following manufacturer’s directions for impression material chosen. A material that allows two pours is recommended. Alternatively, two impressions may be made.
 - 3.2 Prepare and place provisional restoration on the prepared tooth. Use non-eugenol containing material(s).

3.3 Two casts will be fabricated. One working cast will be indexed and separated, per usual crown and bridge procedures. The second master cast will be used for final contour adjustment. Following impression material manufacturer's instructions for disinfection and impression casting, use of die stone is recommended for cast fabrication. Plating of the impression is not recommended. Additionally, an opposing cast should be prepared and articulated.

4. Restoration Fabrication

4.1 Block out any preparation undercuts present. Apply separating medium and/or die spacer to separated die. In most cases, the restoration may be fabricated in no more than 3 increments, each up to 4mm depth.

4.2 Apply first increment/shade, creating restoration body. Adapt to die, staying short of margins. Recommended light curing is accomplished by placing in Triad® Light Curing Unit (DENTSPLY Trubyte) for 2 minutes. Apply second, body layer, allowing cut-back for occlusal anatomy and final proximal contour. Repeat Triad® Light Curing. Prior to final "enamel" shade placement, custom staining with appropriate compatible stains may be accomplished per manufacturer's instructions. Apply final layer, slightly overfilling and covering all margins. Replace die into articulated model. Establish all external, proximal and occlusal contacts and anatomy. Slight lubrication of adjacent and opposing model teeth is recommended. Cure briefly (10 seconds) with hand-held visible curing light unit to fix contours. Remove die with restoration, place in Triad Unit for final 2 minute curing.

4.3 When removing restoration from die, it may be necessary to scrape die stone away from restoration margins, to prevent accidental chipping of restoration. Clean any residual die stone from restoration. Carefully trim away visible flash beyond preparation margins with acrylic bur.

4.4 Gently sandblast the internal surfaces with 50m alumina abrasive. Remove visibly undercut material.

4.5 Seat restoration onto preparation of uncut master cast, making adjustments as needed. Check for marginal integrity and overall fit and contour. Additional increments may be added if needed by roughening surface and applying compatible adhesive per manufacturer's instructions, followed by placement and light curing as outlined above.

5. **Finishing and Polishing (laboratory):** Complete as outlined in the above **Finishing and Polishing Section, Step 7, for Direct Restorations.**

6. **Cementation:** Recommended cementation technique is bonding using a dual cure adhesive and esthetic resin cement such as Calibra® Esthetic Resin Cement and Prime&Bond® NT™ Dual Cure Universal Dental Adhesive System. Follow adhesive and cement manufacturer's instructions for prepared tooth and restoration surface pretreatments.

7. **Adjusting, Finishing and Polishing (clinically):** Following cementation, make all necessary occlusal adjustments and polish any clinically adjusted surfaces as outlined in the above *Finishing and Polishing Section, Step 7, for Direct Restorations.*

CLEANING AND DISINFECTION

To prevent Esthet•X® Restorative material Easy•Twist 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 package contamination. Repeated disinfection may damage label. Do not attempt to clean, disinfect or re-use Compules® Tips. Properly dispose used Compules® Tips.

CLEANING AND DISINFECTION OF TRUMATCH® SHADE GUIDE

The TruMatch® shade guide holder and individual tabs may be cleaned by scrubbing with hot water and soap or detergent.

The shade guide holder and individual tabs if exposed spatter or spray of body fluids or that may have been touched by contaminated hands, or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are EPA-registered as tuberculocidal. Disinfect the shade guide holder and individual tabs by spraying the shade guide holder and individual tabs with any recommended hospital-level dual or synergized quaternary ammoniums or immersing in hospital-level disinfectant such as dual or synergized quaternaries or glutaraldehyde for the contact time recommended by the disinfectant manufacturer for optimum results. Spraying with glutaraldehyde is not recommended. Chlorine based (bleach), some phenolic-based agents and iodophor-based products should not be used as they may cause surface staining and/or color alteration. Agents containing organic solvents, such as alcohol, should be avoided, as they may tend to dissolve the plastic. Water-based disinfectant solutions are preferred. The disinfectant manufacturer's directions should be followed properly for optimum results.

Following disinfection, thoroughly rinse and dry the TruMatch® shade guide holder and individual tabs before storage. Autoclaving the TruMatch® shade guide holder and individual tabs is not recommended.

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 disinfection 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. Compules® Tips Gun is warranted for one year from date of purchase.
3. The following numbers should be quoted in all correspondence:
 - Reorder Number
 - Lot number on Compules® Tip/ Easy•Twist syringe
 - Expiration date on Compules® Tip/ Easy•Twist syringe

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