

**Note:** Prelude One is compatible with both light cured and dual/auto cured composite.

#### STORAGE:

During periods of regular use, store Prelude One at 77°F (25°C) and out of direct sunlight. Refrigeration is recommended. Do not freeze. Allow to come to room temperature before use.

#### DEFINITIONS OF SYMBOLS

The following symbols may appear on the product packaging or labeling.

Symbol	Definition	Symbol	Definition
	Reference number		Lot number
	Use by		Upper limit of temperature
<b>RxOnly</b>	Caution: Federal law restricts this device to sale by or on the order of a dentist.		European Community Authorized Representative
	Manufacturer		European Mark of Conformity
	Keep away from sunlight		Consult instructions for use

Prelude One Unit Dose is not approved by Health Canada.

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# Prelude One™

**RxOnly**

#### PRODUCT DESCRIPTION

Prelude One is a light-curable single component self-etch adhesive designed to bond composite resins to most dental surfaces. These surfaces include dentin, enamel, zirconia, alumina, metals, porcelain, lithium disilicate, and composite restorations.

#### INDICATIONS FOR USE

Prelude One is a primer and adhesive used for:

- Conditioning of zirconia, alumina, and metal definitive restorations prior to cementation, e.g., crowns, posts, inlays, and onlays
- Adhesive repair of defects in zirconia, alumina, metal and composite restorations currently affixed to a patient's dentition
- Adhesive for bonding composites and other dental restorative materials to enamel or dentin

#### PRECAUTIONS

- Read the SDS for safety information. Prelude One contains methacrylate monomers that may produce allergic reactions in some individuals by contact with skin, eyes, or oral mucosa. Always wear suitable personal protective equipment. Patient protective eyewear is recommended.
- Use of this product in any way not specifically described in this Instruction for Use is the sole responsibility of the practitioner. Prelude One is intended for use by a licensed dental practitioner only.
- Use appropriate isolation techniques to prevent saliva and blood contamination of bonding surfaces.
- Do not place Prelude One adjacent to eugenol-containing materials or any other agents that may inhibit the bonding strengths of Prelude One.
- Prelude One is not for direct pulp capping.
- Avoid allowing contact of Prelude One with the oral tissue.
- Do not allow pooling of the adhesive.
- Always keep Prelude One away from sources of heat, including, but not limited to, direct sunlight. Refrigeration is recommended.

#### INSTRUCTIONS FOR USE

Please keep 'Instructions for Use' as a reference guide during all procedures as an easy guide for use. They are meant to help the user as a guide when using Prelude One and should be only used as noted.

#### TOOTH PREPARATION

##### Self-etching technique:

- Prepare cavity preparation by removing all debris with spray of oil free water and blot with clean cotton pellet or air dry with oil free air.
  - ▶ Do not desiccate the tooth surface.

##### Total-etching technique:

1. Prepare cavity preparation by removing all debris with spray of oil free water.
2. To further enhance bond strength, the enamel may be selectively etched. This step is optional.
  - Apply a commonly used phosphoric acid containing etching materials onto the prepared and unprepared (if present) enamel and dentin and allow etching for 15 seconds.
  - Rinse thoroughly with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
  - Do not desiccate the tooth surface.

### Enamel selective-etching technique:

1. Prepare cavity preparation by removing all debris with spray of oil free water.
2. To further enhance bond strength, the enamel may be selectively etched. This step is optional.
  - Apply a commonly used phosphoric acid containing etching materials onto the prepared and unprepared (if present) enamel and allow etching for 15 seconds.
  - Gently rinse thoroughly with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
  - Do not desiccate the tooth surface.

### Unprepared Tooth Enamel

1. A commonly available clinical method (e.g. polishing paste or powder blasting) should be used to clean the enamel surface. Gently rinse thoroughly to remove all debris with oil free water spray and air dry with oil free air.
2. Continue by the use of "Enamel selective-etching technique" or "Total-etching technique".

**Note:** To have the best performance, always prepare and etch tooth enamel.

### PREPARATION FOR REPAIRS

#### Preparation of Composite Restorations

1. Remove all the loose and cracked sections of an existing restoration with a rotary bur or other dental abrasive instruments (e.g. Danville MicroEtcher).
2. Gently rinse thoroughly to remove all of the residue and debris and thoroughly clean with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
  - Do not contaminate.
  - The surface should appear chalky- if not repeat 'sand blasting' and thoroughly clean
3. Apply Prelude One as directed below.

#### Preparation of Silica based materials- Lithium Disilicate, Feldspathic Porcelain:

1. Remove all the loose and cracked sections of the restoration with a rotary bur or "Sand Blasting" (e.g. Danville MicroEtcher) using  $\leq 50\mu\text{m}$  aluminum oxide powder with HVS (high volume suction), abrade all surface to be repaired.
2. With the use of a rotary diamond abrade all surface to be repaired.
3. Gently rinse thoroughly to remove all of the residue and debris and thoroughly clean with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
  - Do not contaminate.
4. For the best results, etch 'repairing' surfaces with hydrofluoric acid for 15 seconds. Then gently rinse thoroughly to remove all of the etchant and clean with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
5. Apply a dental silane primer for ceramic materials suitable with acrylates.
6. Apply Prelude One as directed below.

**Note:** The use of etching with phosphoric acid will weaken the adhesion.

#### Preparation of Non-Silica based materials including Zirconia, Alumina, Porcelain, Precious Metal, Non-precious Metal:

1. Remove all the loose and cracked sections of the restoration with the use of a rotary diamond or "Sand Blasting" (e.g. Danville MicroEtcher) using  $\leq 50\mu\text{m}$  aluminum oxide powder with HVS (high volume suction), abrade all surface to be repaired. Gently rinse to remove all of the excess powder with oil free water spray and blot with clean cotton pellet or air dry with oil free air.
2. Apply Prelude One as directed below.

**Note:** The use of etching with phosphoric acid prior to Prelude One application may weaken the adhesion to all ceramic materials and metals (e.g., Lithium Disilicate, glass ceramics, Zirconia).

### Bottle Delivery

- Always shake the bottle well before use.
- Remove cap from the dispenser bottle and hold the bottle tip vertically straight down.
- Gently squeeze dispenser bottle to dispense 1-2 drops in a clean and unused mixing well
- Replace and tighten cap immediately.
- Keep the adhesive away from direct light and use it as soon as possible.
- Do not cross contaminate.

### Unit Dose Delivery:

- Always shake the unit dose well before use.
- Hold the large end of the Unit Dose in either hand. Grasping the opposite end with the other hand. Firmly apply separating pressure until the two parts separate.
- Insert a disposable applicator into Unit Dose and saturate the applicator tip. Rewet as needed.
- Keep the adhesive away from direct light.
- Do not cross contaminate. Unit Dose is for single patient use only.

### APPLICATION

- To ensure maximum bond strength, cross contamination with external fluids (e.g. saliva, blood or sulcular fluids) should be avoided.
- The use of rubber dam is highly recommended to ensure a dry environment and soft tissue exposure.

### PROCEDURE FOR USE

- **Direct Restorations: bonding composites to dentin and enamel**
- **Intraoral repairs with Light Curing Composites on surfaces of composites, Zirconia, Alumina, Porcelain, Precious Metal, Non-precious Metal, and Lithium Disilicate**
- **Cavity sealing before amalgam placement**

1. Apply copious amount of Prelude One to prepared surface with disposable applicator and scrub for 20 seconds. (For larger restorations, e.g. MOD, apply an additional layer of Prelude One by re-wetting applicator.) Do not light cure adhesive in between layers.
2. With oil free air, gently air dry the adhesive for at least 5 seconds to evaporate solvent. Do not blow away the adhesive. Continue with a stronger air stream (5-10 seconds) until the film no longer moves. The Prelude One should appear glossy.
3. Light-cure Prelude One for 10 seconds with a dental curing light (minimum 600 mw/cm<sup>2</sup>).
4. The surface is now ready for direct restoration to bond a composite.

**Note:** Prelude One is compatible with both light cured and dual/auto cured composites.

- **Indirect Restorations: veneers, crowns, bridges, inlays, onlays (used in conjunction with a luting cement) :**

1. Apply copious amount of Prelude One to prepared surface with disposable applicator and scrub for 20 seconds. (For larger restorations, e.g. MOD, apply an additional layer of Prelude One by re-wetting applicator.) Do not light cure adhesive in between layers.
2. With oil free air, gently air dry the adhesive for at least 5 seconds to evaporate solvent. Do not blow away the adhesive. Continue with a stronger air stream (5-10 seconds) until the film no longer moves. The adhesive should appear glossy.
3. Light cure adhesive for 10 seconds (minimum 600mw/cm<sup>2</sup>).
4. The surface is now ready for cementation with an acrylate or methacrylate based dental luting cement.