



Opal Seal Fluoride Releasing and Recharging Primer User Manual

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Product Description

Opal™ Seal primer is 38% filled with proprietary GI particles and nano fillers that release fluoride during orthodontic treatment. When Opal Seal primer has been applied to the tooth surface the use of a UV black light will make the primer illuminate showing that the resin containing fluoride is present. For all products described, carefully read and understand all instructions and SDS information prior to use.

- 1.2 ml delivery syringe
- Delivery Tips:
 - Metal Opal™ Seal tip

- Opal™ Seal tip

Indications for Use/Intended Purpose

Opal Seal primer is a light cure primer that is used when bonding orthodontic appliances to etched enamel.

Contraindications

- Do not use on patients with known sensitivity to methacrylates or other resins. If dermatitis, rash, or other allergic reaction is observed, rinse exposed area thoroughly and have patient consult their physician.
- For patients or users with allergy concerns, refer to product allergen document available at www.ultradent.com. If allergic reaction is observed, rinse exposed area thoroughly with water and have the patient consult their physician.

Warnings and Precautions

- Resins can be sensitizing. Avoid repeated contact of uncured dental resin with skin and/or soft tissue. If allergic reaction, dermatitis, or rash develops have patient consult their physician.
- Cure bonding resins completely uncured resin materials will be deficient in physical properties, stress, and wear resistance.
- Redirect overhead light to prevent premature polymerization.
- Light activated resins are sensitive to ambient light; when not in use, ensure cap is secured onto syringe or capsule.
- Patient and dental professionals must wear protective eyewear with side shields.
- If the product is ingested, drink large amounts of water and contact a physician. If the product is aspirated, seek immediate medical attention.
- Use only recommended tips.
- Tips are single use only.

Stepwise Instructions

Preparation - 1.2 ml Syringe

1. Remove Luer Lock cap.
2. Securely attach recommended tip.
3. Verify flow, color, and consistency prior to expressing intraorally. If resistance is met, replace tip and re-check.

Preparation - Tooth

1. Clean enamel surfaces to be primed with pumice or a similar water-based, mild abrasive.
2. Etch, rinse, and dry all tooth surfaces prior to Opal Seal primer placement.

Use - Direct Bonding

1. Apply a thin layer of Opal Seal primer to the etched enamel.

2. Gently air dry for 2 seconds per tooth to thin. Opal Seal primer should appear shiny, not pooled on the tooth surface. An initial cure of 5 seconds per tooth (on standard mode for curing lights with an intensity of 800 mW/cm² in the wavelength region of 385-515 nm) will help avoid bracket “skating” upon placement.
3. Apply bonding adhesive to brackets according to manufacturer’s instructions and place brackets on prepared teeth.
4. Light cure for 10 seconds on standard mode for curing lights with an intensity of 800 mW/cm² in the wavelength region of 385-515 nm to cure the bonding adhesive, and completely cure the Opal Seal primer. Follow manufacturer’s guidelines to ensure bonding adhesive is completely cured.
5. Opal Seal primer is designed to be re-applied periodically during orthodontic treatment. Shining a UV black light on the tooth will indicate the presence of the primer.

Use - Reapplication

1. With orthodontic wire removed, ensure enamel surface is free of plaque and debris.
2. Prepare exposed enamel around bonded brackets as instructed above.
3. Light cure for 10 seconds per tooth on standard mode for curing lights with an intensity of 800 mW/cm² in the wavelength region of 385-515 nm.

Processing

To avoid cross-contamination, wipe syringe with an intermediate level disinfectant between uses and use a disposable barrier sleeve. If a barrier sleeve is not used, syringe should be treated as single-use.

Storage and Disposal

Dispose of waste according to local rules, guidelines, and regulations.

Miscellaneous Information

Report any serious incident to the manufacturer and the competent authority.

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Documents / Resources



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Seal Fluoride Releasing and Recharging Primer, Seal, Fluoride Releasing and Recharging Primer, Releasing and Recharging Primer, Recharging Primer

References

-  [Ultradent Products, Inc.](#)