

Opalescence® Tooth Whitening Systems

Description:

Opalescence® is intended to be a dentist-supervised, take-home bleaching system, dispensed in unit dose syringes. It is a clear, flavored, high-viscosity, sticky, 10, 15, 20, 35%, or 45% carbamide peroxide gel (pH -6.5). Opalescence® PF™ carbamide peroxide and/or hydrogen peroxide gels contain potassium nitrate, fluoride. They also have significant water to reduce shade relapse from tooth dehydration. Opalescence take home products feature sustained release action and adhesive properties. All Opalescence products are gluten-free and kosher.

Indications:

Opalescence has been shown to effectively lighten the internal colors of teeth. In cases of tetracycline, adult monocycline stains and brown fluorosis discoloration, Opalescence has obtained success of varying degrees. This is also true for discolorations caused by congenital, systemic, metabolic, pharmacological, traumatic or iatrogenic factors, erythroblastosis fetalis, jaundice and porphyria. Peroxide is a strong oxidizing agent. Bleaching occurs when the peroxide penetrates the enamel and dentin, oxidizing the offending stains within the tooth. Whitening occurs first and more rapidly with the enamel. For example, most tetracycline stains occur within the dentin and require more time to oxidize (whiten). Because restorative materials will not whiten, we recommend whitening dark teeth before restorative placement, and matching restorations to the new lighter shades (wait two weeks following bleaching procedures before placing restorations).

General Information:

Pay attention to tray design. The sticky, viscous, sustained-release gel behaves differently than other bleaching products and proper tray fabrication will help in avoiding or reducing irritation, limit peroxide contact to tooth surfaces and avoid contact with soft tissues. Following instructions yields results in days rather than weeks. The gel will stay active 8-10 hours in the mouth. Advise your patients on the following recommended wear times: Opalescence 10% for 8-10 hours or overnight; Opalescence 15% for 4-6 hours; Opalescence 20% for 2-4 hours; Opalescence 35% for 30-60 minutes; and Opalescence Quick 45% for 15-30 minutes. Observing wear times and properly using Opalescence can speed results and reduce long-term exposure to peroxide. A soft, thin tray material is best for fabrication of custom trays (Sof-Tray® 0.035) because it is more comfortable and the thin material occupies less of the patient's interocclusal space thereby minimizing awareness of the tray.

Pre-Treatment Procedure:

1. A diagnosis to ensure dental health must precede a bleaching treatment. Address failed restorations and/or areas of caries with temporary restorations. Exposed root surfaces may experience sensitivity, and if large areas are exposed, or if restorations are inadequate, patients may develop mild to moderately severe pain. Sometimes this can be addressed by simply trimming the tray back or covering exposed root surfaces with a bonding agent.
2. Remove calculus and extrinsic stains. If tissue is traumatized, wait one to two weeks before beginning bleaching treatment to minimize possible gingival sensitivity.
3. Wait two weeks following the bleaching procedure before matching and placing resin-bonded restorations, because color stabilization requires time and because residue peroxide ions will interfere with bond strengths. This is important before placing definitive tooth-colored restorations.
4. Occasionally, a slight purple discoloration may appear in the tray following bleaching adjacent to amalgam fillings. This discoloration is normal.
5. Teeth with large amalgam restorations may appear darker than other bleached teeth because the internal restoration becomes more visible through the bleached enamel. The patient should be made aware that this may require a more extensive esthetic restoration following bleaching.
6. Some teeth do not respond to bleaching and occasionally the original tooth colors return shortly after completion of treatment. This may be caused by a temporary color shift from dehydration (and then rehydration) of the teeth. Where enamel is thinner, tooth will appear darker.
7. When not in use, trays should be stored in the appliance cases provided in each Opalescence kit.
8. Dark, non-vital, endodontically treated teeth are rapidly whitened by opening lingual access of tooth. The patient is given an Ultradent® syringe with a Black Micro® tip and instructed to irrigate lingual opening with water, then fill opening with Opalescence. The tray is then loaded and inserted. Evaluate periodically, as non-vital teeth can whiten significantly in 1-4 days.
9. If patient is unable to follow the treatment safely, this whitening treatment should not be recommended.

Procedure:

1. Fabricate the tray using laboratory instructions or send a working cast/model with a prescription order form to Ultradent.
2. Use the provided patient instructions to instruct patient on the bleaching procedure, application of Opalescence, cleaning technique and tray care. Explain treatment regimens to patient:
 - a. Most dentists prefer nighttime bleaching regimens for their patients because they offer maximum results with less bleaching material use, due to decreased salivary flow during sleep. The lowered mouth activity prevents "pumping" of material from tray. Wear Opalescence 10% 8-10 hours or overnight, Opalescence 15% 4-6 hours, Opalescence 20% 2-4 hours, Opalescence 35% for 30-60 minutes, and Opalescence Quick 45% for 15-30 minutes.
 - b. Alternative, treatments can be used from 30 minutes to several hours per day, depending on the patient's needs, level of sensitivity and day-to-day activities.
 - c. Stopping for multiple nights does not jeopardize continued bleaching when re-initiated.
3. Demonstrate how to load tray by expressing one continuous bead of gel approximately half way up (or slightly lower) from the incisal edge on the facial side of the tray from molar to molar. This should use no more than 1/3 to

1/2 of a syringe. Instruct patient to clean tray with a soft toothbrush and tepid tap water after each use.

4. Occasionally tooth sensitivity and/or gingival irritation may require treatment. The treatment of choice is UltraEZ®, a sticky, viscous gel that contains potassium nitrate and is worn in the Opalescence bleaching tray for up to one hour. Alternative treatments include the following:
 - a. Patient may wear tray with a near-neutral, sticky viscous, fluoride gel (Flor-Opal®). Daytime use insulates teeth from cold, allowing sensitivity to subside.
 - b. Appropriate administration of mild anti-inflammatory analgesics. Consult a doctor and/or pharmacist for drug interactions.
5. Evaluate patients every 3-5 days of treatment depending on patients' needs and degrees of progress. The number of days required for complete treatment depends on the type and severity of. For example, tetracycline stains require more treatment time than other types of stains.

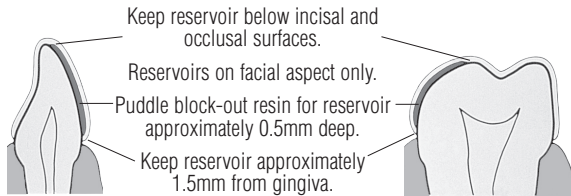
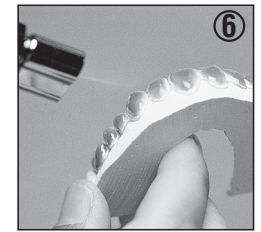
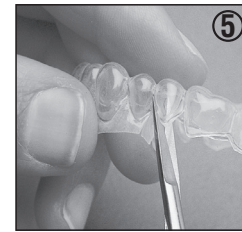
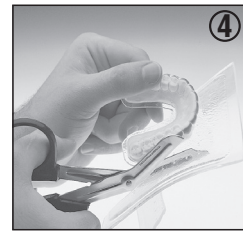
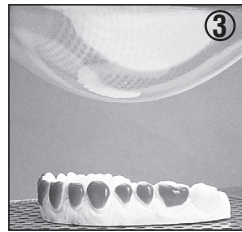
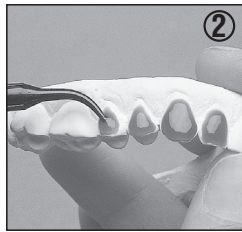
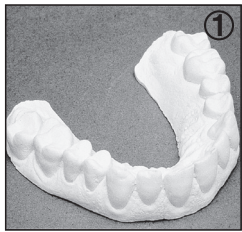
Precautions:

1. Read and understand all instructions. Use recommended tray design and administer appropriate treatment regime to maintain optimal patient comfort.
2. Ensure gingival and general oral health prior to initiating treatment.
3. As a safety precaution, Opalescence should NOT be used during pregnancy. Consult a healthcare practitioner if you are breastfeeding or pregnant.
4. If patient has a known allergy or chemical sensitivity to peroxides, Carbopol, glycerin, etc., Opalescence is NOT to be used.
5. Mint and melon flavors can be irritating to some patients. If patient has a known sensitivity to mint or melon, use alternate flavors.
6. Restorations should be adequately sealed and all exposed sensitive dentin should be covered. If a history of sensitivity exists, treat with appropriate restoration, dentin bonding agent, or temporarily with dentin sealant.
7. Hypocalcified areas, which may not be visible to the naked eye, will whiten faster, thereby becoming more obvious during bleaching. Continue bleaching treatment until the unaffected tooth surface blends. Re-evaluate two weeks after bleaching treatment when tooth color has stabilized.
8. Monitor patient's progress every few days, depending on severity of tooth discoloration. If only a mirror change is desired, evaluate the patient's progress within 1-3 days. Since some teeth become more translucent with bleaching, observe teeth with large metallic fillings closely to detect and prevent show-through.
9. If gingival or tooth discomfort persists (such as excessive temperature sensitivity), inform patient to discontinue treatment and make an appointment for evaluation.
10. Maintain control of Opalescence whitening agent, dispensing only what is needed to reach the next evaluation appointment (approximately 3 to 5 days).
11. Monitor patients' bleaching progress to prevent bleaching beyond the desired level of whitening or degree of translucency.
12. Understand each patient's expectations before beginning treatment. Inform patients that existing crowns, tooth colored fillings, etc., do not whiten. Also, for a small percentage of the population, their teeth will not appreciably whiten.
13. Opalescence whitening agent is supplied in preloaded 1.2ml unit-dose syringes. Material is NOT to be injected, and patients should be instructed to dispose of syringes when empty.
14. Instruct patients to keep Opalescence out of heat and/or direct sunlight.
15. Patients with heavy occlusion or bruxers may require a thicker 0.060" tray.
16. Avoid treatment if patient may swallow or aspirate tray.
17. Instruct patients to be careful not to swallow gel or rinsed gel. Opalescence tooth whitening products contain peroxide and may contain fluoride and potassium nitrate; swallowing large amounts can be harmful.

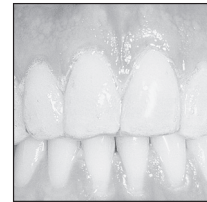
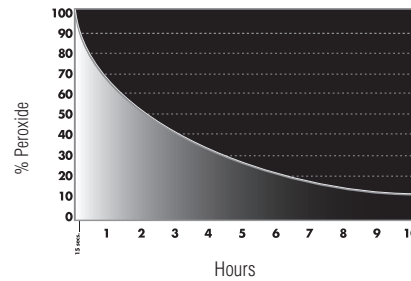
Laboratory Instructions:

1. Pour impression with fast set plaster or dental stone. Pour alginate shortly after making impression to ensure accuracy. Trimming is less work if quantity of stone is kept to a minimum. However, have enough mass to ensure removal of model from impression without fracture. Trim base of cast parallel to the occlusal table on model trimmer to within a few millimeters of gingival margin for ease of manipulation. Palate and tongue areas are not poured or should be removed after plaster has set. Allow model to dry two hours.
2. Ultradent® LC Block-Out provides reservoir spaces in tray. Apply 0.5mm thickness of material onto desired labial surfaces and approximately 1.5mm shy of the gingival margin. DO NOT extend onto incisal edges and occlusal surfaces. This prevents tray margins from flexing open upon biting and/or impinging on soft tissues. Cure LC Block-Out by slowly scanning the resin for approximately 2 minutes (VALO®, VALO GRAND®). A hand-held intraoral curing light can be used (5 seconds per tooth). Wipe off oxygen inhibition layer.
3. Place tray material in a vacuum former (UltraVac™ or use Econo Vacuum Former), and heat until it sags approximately 1 inch. Activate vacuum and adapt softened plastic onto model. Cool and remove model from the vacuum former. To avoid distortion, cool the tray material completely before removing from the model.
4. Cut excess bulk of material away with serrated plastic trimmers (Ultradent® Utility Cutters).
5. With small tactile scissors (Ultra-Trim™ Scallop Scissors), carefully and precisely trim the tray to clear line which is at the gingival height, flaming edges to reduce to desired height. To avoid discomfort and irritation of the gingival papillae, scallop into the gingival.
6. Return tray to model; check tray extensions. Gently flame polish edges, one quadrant at a time, with a butane torch. While still warm, immediately hold periphery of each segment firmly against model for three seconds with water-moistened gloved finger. If an area is short of the desired length, gently heat and push the tray material to the desired location. If this over-thins the tray material, fabricate a new tray.
8. Once tray is fabricated, clean with a soft brush and anti-microbial mouthwash rinse. Store tray in appliance case when not in use.

Ultradent Products, Inc.
Attn: Tray Fabrication
505 West Ultradent Drive (10200
South) South Jordan, Utah 84095



Sustained Release Test: After dental examination, Opalescence-filled customized tray (plastic membrane) was inserted. Small quantities of gel were removed at various intervals throughout the night for analysis of percentage of active ingredient.¹

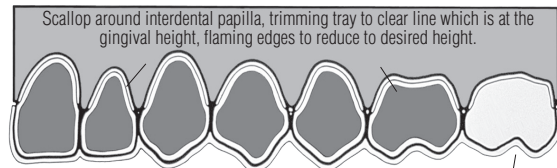


Stay shy of gingiva, scalloping around interdental papilla.



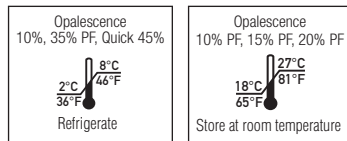
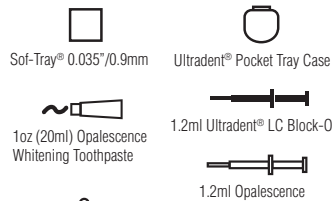
Lapping onto gingiva may irritate tissues.

¹ MATIS, BRUCE A., et al. "In vivo degradation of bleaching gel used in whitening teeth." The Journal of the American Dental Association 130.2 (1999): 227-235.

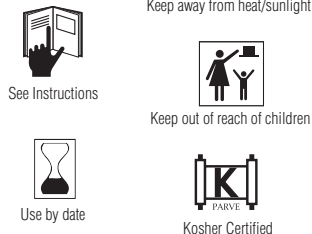


If one or more teeth are much darker than others (e.g. overly dark cuspid(s)), build reservoir(s) on that/those teeth only to balance end whitening results. Teeth of lower esthetic concern need not receive reservoir.

DOCTOR INSTRUCTIONS



Opalescence®
tooth whitening systems



For professional use only.
All Opalescence products are Gluten Free
For immediate reorder and/or complete descriptions of Ultradent's product line, refer to Ultradent's catalog or call Toll Free 1-800-552-5512. Outside U.S. call (801) 572-4200 or visit www.ultradent.com.

For product SDS please see our website:
www.ultradent.com

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