**I. Description:**
Opalescence® Xtra® is a stable 35% hydrogen peroxide power bleaching, orange premixed gel. It contains a unique, natural light-absorbing, heat-activated chemistry (carotene). It is syringe-delivered for easy dispensing. Activation can be accomplished with a standard curing light. Multiple curing lights can be used for more rapid results.

OpalDam® is a unique, light-reflective, passively adhesive (sealing) light cured resin. Its methacrylate base is designed with adequate strength to maintain a barrier, yet it easily removes from embrasures and undercuts.

**II. Indications:**
Power bleaching is for in-office use only. It is used for dentist-applied bleaching of one or more teeth, parts of a tooth, and/or for accelerated chairside whitening techniques. Opalescence Xtra is also used on nonvital teeth, including intracoronal bleaching.

Opalescence Xtra is an alternative, conservative method for treating dark, discolored teeth (compared to crowns, veneers, etc.). This includes discolorations caused by congenital, systemic, metabolic, pharmacological, traumatic or iatrogenic factors such as dental fluorosis, jaundice, tetracycline and adult minocycline stains, porphyria, trauma, and erythroblastosis fetalis.

Peroxide is a strong oxidizing agent. Bleaching occurs from peroxide penetrating into the enamel and dentin and oxidizing the offending stains within the tooth. Whitening occurs first and more rapidly within the enamel. For example, most of the disfiguring stains from tetracycline occur within the dentin; hence, their oxidation (whitening) requires more time.
Because restorative materials will not whiten, we recommend whitening teeth before esthetic restorative placement (wait two weeks after bleaching procedures before placing adhesive restorations). Bleaching problematic teeth to a more natural shade will optimize shade matching. Use Opalescence Xtra alone or in conjunction with the dentist-supervised Opalescence Take-Home Bleaching System. Our experience shows that most treated teeth continue to whiten 12-24 hours after treatment.

OpalDam is used to protect soft tissue adjacent to the teeth during in-office bleaching, microabrasion, etc.

III. Preliminary Procedures:
1. Remove any calculus or extrinsic stains before the bleaching appointment.
2. Instruct patient to gently brush and floss well before beginning procedure. Food debris and plaque will diminish peroxide.
3. Determine and record shade before bleaching.
4. Shield patient's and clinician's eyes with UV orange protective eyewear with side shields.

IV. Isolation:
Isolate teeth to be bleached with OpalDam light cured resin (Figs. 1-3) or with conventional rubber dam (we recommend powder-free DermaDam®) with OraSeal® Caulking (Figs. 9-11). If bleaching only one or a few teeth, OpalDam is the gingival barrier of choice.

1. Isolation Procedure Using OpalDam:
   a. Remove luer lock cap and attach a disposable Black Micro® tip securely onto OpalDam syringe.
   b. Place self-supporting plastic cheek retractors. Completely rinse and air dry teeth, paying special attention to the gingival third. Note: When isolating the mandibular arch, prevent saliva from flowing through embrasures of anterior teeth by using saliva ejector and cotton rolls in the sublingual region. Express the OpalDam through the embrasures, onto cingulums, and on adjacent gingiva. Light cure as directed in Id.
   c. Express OpalDam resin to build a 4-6mm by 1.5-2mm thick strip onto gingiva. Lap approximately 0.5mm onto enamel (Fig. 1). If excess resin flows onto enamel, “tack” area for 5 seconds with curing light and use a hand instrument to trim back excess. Extend resin beyond the last tooth to be bleached (Fig. 2). Where open embrasure(s) exist, express resin through the opening onto lingual, filling embrasure space completely. This will protect interdental papilla and lingual gingival tissue. Resin buttons extending through gingival embrasures add retention to OpalDam barrier.
      Note: Once the critical areas (gingival margins and embrasures) are covered using the Black Micro tip, the Black Mini® tip may be used to cover the larger areas of the buccal mucosa more rapidly.
   d. After resin barrier is applied, cure resin with a quality curing light 20 seconds per light guide width. Note unique light-reflective properties of OpalDam! (Fig. 3). Clean teeth with prophy paste to remove any excess resin film. Use caution not to dislodge cured OpalDam barrier.
   e. OpalDam works nicely for full arch bleaching. Place a tongue/bite block (we recommend IsoBlock®) in molar region and instruct patient to hold it in place with gentle but firm biting pressure. Place cotton rolls into vestibule.

2. Alternative Isolation Procedure Using Rubber Dam:
   a. For safety, ligate rubber dam clamps with floss. Place appropriate clamps, bilaterally, one tooth posterior to teeth being whitened.
   b. Punch holes and position rubber dam over clamps and teeth.
   c. Before attaching rubber dam onto frame, extrude an even bead (~2-3mm wide) of OraSeal Caulking along contours of free gingiva, including interproximal areas, to develop a seal (Fig. 9).
d. Attach rubber dam to frame. Using a rubber dam instrument or an Ultradent Slide Packer and air, invert rubber dam border around teeth for maximum tooth exposure and optimum rubber dam seal (Figs. 10 and 11).

V. Application of Opalescence Xtra:
1. Remove luer lock cap from syringe and attach a disposable tip. Ultradent recommends using the Inspiral® Brush tip or Black Mini brush tip depending on the doctor’s preference.
2. Check material flow on an inert surface (e.g., mixing pad) to ensure evenness of flow before using intraorally. If resistance is felt, DO NOT proceed. Attach a new tip and test again before using on patient.
3. Apply approximately 1.0mm thick layer of Opalescence Xtra bleaching gel over labial surfaces (Fig. 12). Extend slightly onto incisal/occlusal edges.

VI. Light Activation:
1. Use largest light guide available; ideally 10-12mm in diameter.
2. Hold light guide close to gel (~0.25" from surface). Expose each tooth 20-30 seconds. For plasma-arc, laser and high intensity lights 3-5 seconds of exposure time is sufficient.
3. 10-15 minutes after gel application, remove Opalescence Xtra from teeth using suction only (Fig. 4). To prevent Opalescence Xtra from splattering on to soft tissues, DO NOT use water during suction. After all visible gel is removed, follow with a thorough rinse and high-volume suction (Fig. 5). Air dry teeth. Use caution not to dislodge resin barrier.
   Note: If at any time patient experiences discomfort, discontinue bleaching the sensitive tooth (teeth); Proceed to “Cleanup” below, reschedule in 3-5 days for next treatment should additional whitening be desired.
4. If additional whitening is desired, and no significant tooth sensitivity is observed, apply fresh gel and repeat steps 1-3. If bleaching multiple teeth, move across arch re-heating gel periodically. Every 10-15 minutes inspect gel and whiteness.
   Note: If only 1-3 teeth are being treated, expose with curing light for 1-5 minute intervals, or until patient indicates discomfort. If additional whitening is desired, additional in-office whitening can be performed with a bleaching tray and Opalescence® Quick™ 35% carbamide peroxide gel; Opalescence take-home bleaching system (Fig. 14); or reschedule in 3-5 days for additional in-office “power” bleaching with Opalescence Xtra.

VII. Cleanup:
1. For OpalDam:
   a. After thoroughly vacuuming off whitening gel, rinse teeth with air/water syringe and vacuum. Lift OpalDam barrier from surface using an explorer or instrument. All or large pieces will usually lift off at one time (Fig. 6).
   b. Remove OpalDam interproximally using explorer and/or floss. Rinse interproximally with firm air/water spray (note results in Figs. 7 and 8).
2. For Rubber Dam:
   a. After thoroughly vacuuming off whitening gel, rinse teeth with air/water syringe and vacuum. Remove clamps and rubber dam.
   b. Remove bulk of OraSeal with a spatula. Remove residual by rinsing while using a soft toothbrush and vacuum. A firm air/water rinse and dental floss may be necessary interproximally.
   c. Check interproximally for remaining debris. Use floss and firm air/water spray to clean interproximally.
VIII. Notes:
1. Bleaching heat lamps may be used following standard safety protocols to activate Opalescence Xtra. However, more appointments may be required to achieve the desired results.
2. Opalescence Xtra may be used in conjunction with the take-home, 10% carbamide peroxide Opalescence Tooth Whitening Gel to blend in-office treated anterior teeth to posterior teeth. Usually 2-4 nights treatment is sufficient (Fig. 14). Wait 24 hours after in-office procedure before starting patient on dentist-supervised home bleaching to minimize sensitivity.
3. Should patient experience post-op sensitivity, dentist can prescribe UltraEZ® potassium nitrate gel in a tray 3-6 hours per day until condition subsides.
4. Opalescence Xtra is uniquely close to neutral pH. Other power bleaching gels are usually acidic and require difficult, messy chairside mixing.
5. Etching before bleaching does not potentiate the bleaching process and is not recommended with Opalescence Xtra. Opalescence Xtra is not dependent upon opening the “enamel pores” with acid.

IX. Non Vital Teeth:
1. Open lingual access to pulp chamber and remove all composite, base material, and gutta percha 2-3mm apical to the CE junction. Place a glass ionomer base 1mm thick to ensure a barrier between the “sealed” root canal and bleaching gel.
2. Follow “Isolation” instructions above for OpalDam technique.
3. Apply OpalDam resin to both the labial and lingual gingiva of the dry, nonvital tooth, extending about 0.5mm onto tooth (Fig. 16). Light cure 20 seconds.
4. When bleaching a single, nonvital tooth, insulate adjacent vital teeth from the curing light heat by covering the adjacent half of the vital tooth with a thick layer (3-4mm) of OpalDam resin (Figs. 15 and 16).
5. Express Opalescence Xtra into the opened pulp chamber and onto the labial surface (Fig. 17).
6. Use curing light to activate whitening gel from labial and lingual. Two curing lights can be used simultaneously for quicker results (Fig. 18).
7. Expose each tooth 20-30 seconds. For plasma-arc, laser and high intensity lights 3-5 seconds of exposure time is sufficient. After 5 minutes total exposure with curing light (1 minute total for plasma-arc, laser and high intensity lights), remove Opalescence Xtra from teeth using suction only. Follow with a thorough rinse and high-volume suction. Air dry teeth. Use caution not to dislodge resin barrier.
8. Repeat steps 1-6 until desired results are achieved. If significant results are not achieved in 20-30 minutes (cumulative time per tooth), discontinue.
9. If vital teeth are being whitened in conjunction with the nonvital tooth, follow “Application” and “Light Activation” procedure.
10. When desired color is reached, follow “Cleanup” procedure as previously instructed (note results in Figs. 19 and 20).
   Note: If pulp chamber is left open for continued tray-delivered bleaching, instruct patient to remove cotton pellet, express gel into the open chamber, then place a filled tray. Instruct patient to insert a new cotton pellet following tray bleaching procedure. Appoint patient for restorative composite two weeks after bleaching is completed.

X. Single- or Partial-Tooth Bleaching:
1. The recommended barrier technique for single tooth bleaching is “Isolation Procedure Using OpalDam” (page 2). The rubber dam technique may be used if desired.
2. Apply Opalescence Xtra to discolored or stained tooth (or part of tooth). Use curing light to activate according to instructions above.
3. Repeat procedure until desired results are achieved.
   Note: If multiple surfaces or larger areas are involved, multiple curing lights can be used simultaneously for quicker results. If at any time patient experiences discomfort, discontinue bleaching and go to “Cleanup” procedure.
4. Re-warm every 1-3 minutes depending on light used.
5. “Clean up” as instructed in Section VII.

XI. Precautions:
1. Check material flow on an inert surface (e.g., mixing pad) to ensure evenness of flow before using intraorally. If resistance is felt, DO NOT proceed. Attach a new tip and test again before using on patient.
2. Refrigeration is required to maintain shelf life. Keep out of heat and direct sunlight.
3. Wear protective gloves and eye covering when handling this product! Hydrogen peroxide is a strong oxidizing agent and can cause burns. Keep isolated to area of treatment. Vacuum gel off teeth before rinsing with water to prevent splattering.
4. Clinician and patient must wear UV orange protective eyewear with side shields when using curing light to avoid bright light and/or chemical injury.
5. Gingival and general oral health should be confirmed before treatment.
6. Although there is no evidence to the contrary, because of safety precautions, DO NOT use Opalescence Xtra on patients who are pregnant or nursing.
7. Opalescence Xtra is contraindicated for patients with known allergy or chemical sensitivity to peroxides or glycols.
8. Restorations should be water-tight, and all exposed sensitive dentin should be covered. If areas are sensitive or potentially so, treat with proper restoration, dentin bonding agent, etc.
9. OpalDam should not be used with dental whitening agents other than Opalescence Xtra. Use only a quality curing light when polymerizing the OpalDam resin.

Fig. 21 Note recurring bubbles in bleaching gel along gingival border of barrier. Leakage, materia alba, or food particles may be the cause.
10. Larger recurring bubbles in Opalescence Xtra may indicate leakage of peroxide gel onto gingiva or presence of organic debris (Fig. 21). Vacuum off gel, wash, dry, and inspect. If leakage appears to be the problem, reseal area with OpalDam resin.

11. Areas of hypocalcification, clinically not visible, occasionally exist. Because of mineralization differences, these areas will whiten faster than normal enamel and will become more visible during bleaching. Continue bleaching until remaining tooth surface more closely blends with hypocalcified area (additional blending usually occurs later during normal rehydration following completion of bleaching). Additional appointments and/or dentist-supervised tray bleaching may be required. Re-evaluate in two weeks when color has stabilized.

12. Determine and understand patients’ expectations before beginning treatment. Inform patients that existing composite restorations, crowns, and bridges do not lighten. Inform patients that because of unforeseen factors or enamel variations, some teeth may not meet desired expectations.

13. Caution should be used to prevent transfer of Opalescence Xtra gel to adjacent tissue(s) from inadvertent contact from gloved finger, vacuum tip(s), curing light, etc. Affected tissues should immediately be rinsed clean with lots of water.

14. Clinician should wait two weeks following the bleaching procedure before matching restorations to tooth shade to ensure stabilization of color and to ensure all peroxide has leached from the enamel and/or dentin. Residual peroxide (oxygen) in the tooth will prevent adequate bonding.

15. Monitor patients’ bleaching progress during procedure and with take-home gel to prevent over-bleaching and/or excess enamel translucency.

16. Some enamel stains do NOT respond to bleaching. Inform your patient of this possibility before treatment. Opalustre® microabrasion slurry may be used on surface stains that do not bleach.

17. Opalescence Xtra is supplied in preloaded 1.2ml unit dose syringes. Material is NOT to be injected. When empty, dispose of syringes properly. Avoid disposing of syringes in receptacles containing combustible products. Strong peroxides can initiate combustion.

18. Do not use OpalDam on patients with known sensitivity to resins. If dermatitis, rash or any other allergic reaction develops, wash area with lots of water and refer patient to a physician.

19. Partially used syringes may be cleaned and disinfected between patients. Use Ultradent® Syringe Covers sealed with the Ultradent® Impulse Sealer for a protective barrier against cross-contamination.

20. There are some indications that peroxides could potentiate the action of some carcinogens. As a precaution, patients who use tobacco or alcohol products should discontinue their use during the bleaching procedure, whether done in the office or tray-delivered at home.


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1 Studies (two examples below) and clinical experience show that quality of light varies from curing light to curing light. Effectiveness of light and light conducting fibers, tubes, etc. decreases as unit ages. Light cure units should be checked to ensure that maximum light is being delivered for proper curing. Lower intensity lights may require additional exposure time. Check with curing radiometer.


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Shelf life: 12 months

Refrigeration Required!

Keep Out of Reach of Children! • Handle With Care!

For Professional Use Only.
Opalescence Xtra
Flammability
Health
Reactivity

MSDS Required & Included.

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