Opalescence® Boost® 40%

Tooth Whitening System

Description:

Opalescence Boost 40% is a hydrogen peroxide, in-office whitening gel. The 2-barrel jet mix syringe ensures maximum strength for each application and precise dosing of the activator. One barrel contains 1.1% sodium fluoride and 3% potassium nitrate, along with a unique chemical activator, which is combined with a second barrel containing hydrogen peroxide. The final hydrogen peroxide concentration is 40%.

Indications for Use:

Opalescence Boost 40% whitening is for in-office use only. It is applied by the dental professional for bleaching one or more teeth. Opalescence Boost in-office whitening is also used on non-vital teeth, including in-office intracoronal bleaching.

Opalescence Boost in-office whitening is an alternative, conservative method (compared to crowns, veneers, etc.) for bleaching dark, internally discolored teeth caused by predisposing factors such as disease, traumatic or iatrogenic injury, congenital, systemic, metabolic or pharmacological influences. These can include but are not limited to jaundice, tetracycline and adult minocycline stains, porphyria, erythroblastosis fetalis and high fluoride intake during tooth development.

Preliminary Procedures:

- 1. Clean and polish teeth approximately two weeks prior to bleaching appointment.
- 2. Determine and record baseline shade. Use photographs when indicated for baseline documentation.
- 3. Prior to mixing, bring Opalescence Boost in-office whitening to room temperature.
- WARNING: Patient, clinician and assistant must wear protective eyewear and gloves when mixing and applying this product.

Directions for Use:

Mixing Opalescence Boost in-office whitening (Fig.1):

- Check syringes are securely attached.
- Depress the small clear plunger into the middle small clear syringe to rupture internal membrane and combine bleach and activator.
- 3. Press the plunger of the red syringe in, pushing all contents into the clear syringe.
- 4. Press the clear plunger completely back into the red syringe.
- 5. To thoroughly mix activator with bleaching gel, push stems back and forth continually with thumbs and mix a minimum of 50 times rapidly (25 times each side).
- Press all mixed gel into the RED syringe.
- Twist to separate the two syringes and securely attach the recommended tip (Micro 20ga FX® tip, Micro 20ga tip, or Black Mini® tip) onto the red syringe.

Isolation - OpalDam® resin barrier (recommended isolation):

- 1. Place Ultradent IsoBlock™ bite block and self-supporting lip/cheek retractors. (Fig.2)
- 2. Remove Luer lock cap from OpalDam resin barrier and securely attach a Micro 20ga tip.
- 3. Verify flow prior to applying intraorally.
- 4. Rinse and dry teeth and gums thoroughly.
- 5. Express a continuous bead of OpalDam resin barrier along the gingival margin, overlapping approximately 0.5mm onto the enamel. Begin and finish the bead one tooth beyond the most distal tooth that is being bleached.
- 6. Continue building the barrier apically until it is 4-6mm high and 1.5-2.0mm thick. (Fig.3)
- Express resin through any open embrasures onto the lingual tissue to completely seal and cover exposed papilla.
- 8. Using the mouth mirror, look up the long axis of the teeth for gaps or minute openings exposing the underlying tissue and re-apply resin.
- Light cure 20 seconds per arch using a scanning motion. Carefully check resin cure with an instrument. (Fig.4)

Isolation - Rubber Dam:

- 1. Apply rubber dam placing ligated clamps bi-laterally and one tooth distally to the teeth to be
- 2. Before attaching rubber dam to the frame, apply a bead of rubber dam sealer at the gingival

margin beneath the dam.

- 3. Attach dam to the frame and invert rubber dam at the gingival border. Check for optimum seal. **Applying Opalescence Boost in-office whitening:**
- On gauze or mixing pad, verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check. Use only recommended tips.
- NOTE: If resistance continues, DO NOT use that syringe and contact Ultradent Customer Service for replacement.
- 2. Apply a 0.5-1.0mm thick layer of gel to the clean labial surface of the tooth.
- Allow gel to remain on the teeth 20 minutes, periodically checking and re-applying areas that have thinned or need replenishing.
- 4. Suction gel from teeth using the Luer Vac and SST™ (Surgical Suction Tip) or a surgical suction tip. To avoid gel splatter, do not use water while suctioning gel (Fig.6). When no gel is visible, lightly rinse and air dry. Use caution not to dislodge the isolation barrier or rubber dam seal.
- 5. Evaluate shade change after each application and monitor patient for sensitivity and irritation.

 If persistent tooth sensitivity occurs, discontinue use.
- 6. Avoid contact with soft tissue or salivary flow. If chemical irritation occurs due to the intraoral soft tissue coming in contact with the hydrogen peroxide gel, immediately wipe the gel from the tissue using a wet gauze and rinse the area well. Tissue should return to normal within 20-30 minutes.
- Repeat steps 2-5 up to two additional times if desired results have not been achieved. Do not
 exceed 3 applications per visit.
- If additional in-office whitening is desired and no significant sensitivity is noted, re-schedule
 and retreat patient as desired. If sensitivity was experienced, repeat treatment when the
 sensitivity has subsided.

Clean-up:

- Suction gel from teeth using the Luer Vac and SS™ (Surgical Suction Tip) or a surgical suction tip, then thoroughly rinse teeth with an air/water spray and the high volume suction. (Fig.7)
- Using a dental instrument, gently slide the tip beneath the OpalDam resin barrier and lift off. Check and remove any interproximal remnants.
- 3. If using a rubber dam, follow "Clean-up" Step 1, remove clamps, dam, and frame.
- 4. Remove rubber dam sealer with spatula, soft toothbrush, floss, suction and firm air/water spray.

NOTES:

- Whitening is used to return shade of natural teeth to the shade of the remaining nondiscolored teeth or previously matching restoration.
- Whitening effect may continue for 24-48 hours following bleaching, hence a slight increase in whitening may be realized during this period.
- A single, or a few teeth can be bleached using this same instruction and applying the bleach only to those specific areas of discoloration.
- For post-op sensitivity, use potassium nitrate products such as UltraEZ® desensitizing gel immediately after treatment and for 15 minutes to 1 hour per day until sensitivity subsides.
- Additional cosmetic whitening after successful treatment of a single tooth or some teeth is
 possible by either Opalescence Boost in-office whitening gel or a take-home system as soon as
 any sensitivity has dissipated.
- Etching enamel or prophy paste polishing before any bleaching procedure is not recommended and does not potentiate the bleaching process, but can cause sensitivity.

Endodontically Treated Teeth:

- Non-vital teeth can be bleached from both the inside out and the outside in to accelerate
 whitening speed/effectivity.
- Completely remove all the restorative and root sealing material from the coronal area and 2-3mm below the gingiva. Place a 2mm thick conventional glass ionomer or a resin modified glass ionomer, such as UltraCem, to seal the canal.
- Follow the "Mixing" instructions 1-6 above.
- 3. Attach the Micro 20ga tip or Black mini tip. Verify flow prior to applying intraorally.
- Follow "Isolation" instructions above isolating both the labial and lingual sides of the tooth.
 (Fig 8)
- 5. Express into access opening, the labial, and if desired, the lingual surface. (Fig 9 and 10)
- 6. Allow gel to remain in the tooth 20 minutes.

- Suction gel from access opening and tooth using the Luer Vac and SST™ (Surgical Suction Tip)
 or a surgical suction tip. To avoid gel splatter, do not use water while suctioning gel.
- 8. When no gel is visible, lightly rinse and air dry. Use caution not to dislodge the isolation barrier or rubber dam seal.
- Evaluate shade change.
- 10. Repeat steps 5-9 as needed.
- 11. Follow "Clean-up" instructions to remove gingival barriers.
- 12. Seal access with a non-eugenol and non-resin provisional restorative such as UltraTemp® Regular.

NOTES:

- If additional whitening is desired, re-schedule and repeat the Opalescence Boost in-office whitening procedure above or use Opalescence Endo whitening.
- Whitening effect may continue for 24-48 hours following bleaching, hence a slight increase in whitening may be realized during this period.
- Over years, regression is to be expected and re-bleaching on an average of 3-5 years is recommended.

Precautions and Warnings:

- 1. Gingival and oral health should be confirmed before using this product.
- Clinician, assistant, and patient must wear protective eyewear with side shields when mixing and applying Opalescence Boost in-office whitening.
- Restorative materials will not whiten and therefore it is recommended that teeth are whitened prior to placing esthetic restorations.
- 4. Wait 7-10 days after bleaching procedures before placing adhesive restorations.
- 5. Carefully read SDS and all instructions before using.
- 6. Bring syringes to room temperature before mixing.
- Verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check. If resistance continues, DO NOT use that syringe and contact Ultradent Customer Service for replacement.
- 8. Use only recommended tips. Do not reuse tips to avoid cross-contamination.
- 9. To avoid cross-contamination, use a disposable syringe cover, re-cap, and wipe syringe with an intermediate disinfectant between uses. If these measures are not taken, the syringes should be considered single-use.
- 10. Keep out of reach of children.
- 11. Pregnant or breastfeeding women, or patients with serious health concerns should not whiten. Consult their primary care provider prior to treatment.
- 12. Wear protective gloves when handling this product.
- 13. Before disposing of syringes aspirate water into the syringe and express liquid down the drain. Repeat a couple of times before disposing of the syringe. Make sure any gauzes used are rinsed with water.
- 14. Do not use on patients with a known sensitivity to peroxides, glycols, acrylates or other resins. If allergic reaction, dermatitis or rash develops, consult a physician.
- 15. When protecting a full arch, light cure the resin barrier on standard mode using a scanning motion for 20 seconds and keeping the lens approximately 1 cm from the barrier and tissue. When protecting tissue adjacent to fewer teeth, scan the barrier for approximately 3-5 seconds per tooth. With a dental instrument, carefully check resin for a full cure.
- 16. If bubbles occur along the margin of the OpalDam resin barrier after the application of Opalescence Boost in-office whitening gel, suction off gel, rinse and check for leakage. Dry area and re-apply OpalDam resin barrier to the site.
- 17. Cover any sensitive areas of exposed dentin.
- 18. For patients with known tooth sensitivity, pre-op and post-op treatment with UltraEZ desensitizing gel, Opalescence sensitivity relief toothpaste, and/or Enamelast® fluoride varnish is recommended. Depending on the severity of sensitivity, other treatment options are available.
- 19. Areas of hypocalcification, though not clinically visible, may exist and will whiten quicker than surrounding enamel. As patient continues to whiten, the areas will begin to blend.
- 20. All Ultradent syringe-delivered dental materials should never be injected.
- 21. Keep out of direct heat and/or sunlight.
- Opalescence Boost in-office whitening should be used within 10 days of mixing. Keep refrigerated between uses.
- 23. Dispose of tips and syringe as described in above instruction and according to local regulations.

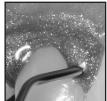
Directions for use:



Fig. 1 Refer to the "Mixing Opalescence Boost in-office whitening" section for mixing instructions.



Fig. 2 Remove any plaque or debris with brush then place Ultradent's IsoBlock bite block.



rier to build a 4-6mm by 1.5-2mm ity curing light by scanning thick strip onto gingiva. Lap approximately 0.5mm onto enamel.



Fig. 3 Express OpalDam resin bar- Fig. 4 Cure resin with a qualthe area for 20 seconds.

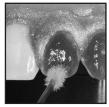


Fig. 5 Apply the Opalescence Boost gel, about 0.5-1.0mm thick, onto labial surfaces. Extend slightly onto incisal/occlusal edge. Tip) or a surgical suction tip.



Fig. 6 Remove Opalescence Boost gel using the Luer Vac and SST™ (Surgical Suction



Fig. 7 Rinse thoroughly directing water toward high-volume suction.

Endodontically Treated Teeth



Fig. 8 Isolate the lingual and labial gingiva and papilla.



Fig. 9 and Fig. 10 After the GI plug is fully set, express Opalescence Boost whitening into the access opening and to the labial and lingual surfaces.



In-Office Whitening



Use by date

Lot Number





See Instructions



Health hazard

Health hazard



Corrosive

Activator Gel

Bleaching Gel



Х026 = гот $X_{02}6 = MM$

X026 = YYYY

For professional use only. Keep out of reach of children. Destroy after use.



1.2ml OpalDam®

light cured resin barrier



Keep away from heat/sunlight



Keep out of reach of children



Recycle







Manufactured by: Ultradent Products, Inc. 505 West Ultradent Drive (10200 South) South Iordan, Utah 84095 USA Made in USA



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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 1-800-552-5512; 801-572-4200



IsoBlock™ Bite Blocks

Delivery Tips



Storage at room

temperature

Patient and clinician must wear safety glasses when product is mixed and applied



Do not re-use to avoid cross contamination

Corrosive



Activator Mixed with Bleaching Gel

Health hazard