

Opalescence™
Tooth Whitening Systems

Description:
Opalescence™ is a dentist-controlled, dentist-supervised, take-home bleaching system, dispensed in unit dose syringes. It is a clear, flavored, high-viscosity, sticky, 10, 15, 20, or 35% carbamide peroxide gel (pH 6-5).

Opalescence™ PF™ carbamide peroxide gel contains potassium nitrate and 0.11% weight to weight (1100 ppm) fluoride ion. Opalescence PF contains potassium nitrate and fluoride. Potassium nitrate has been shown to help reduce sensitivity and fluoride has been shown to help reduce caries and strengthen enamel. Together, they help improve the overall health of teeth. Opalescence gels have 20% water content to lessen tooth dehydration, which minimizes tooth shade relapse.

All Opalescence products have unique qualities, including sustained release, adhesive properties and a custom designed application tray. All Opalescence products are gluten-free and kosher.

Indications:
Opalescence has been shown to effectively remove the internal colors from teeth, from the time of tooth eruption through the stains of aging. In cases of tetracycline and brown fluorosis discoloration, Opalescence has obtained success of varying degrees. Opalescence is also used on non-vital teeth for intracoronal bleaching, and provides a more conservative modality 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, tetracycline and adult minocycline stains, trauma, erythroblastosis fetalis, elevated bilirubin 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 of the discoloring stains for tetracycline 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, because the sticky, viscous, sustained-release gel behaves differently than other bleaching products. To avoid or reduce irritation, limit peroxide contact to tooth surfaces and avoid contact with soft tissues. Following instructions yields predictable results in days rather than weeks. Although the gel stays 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; and Opalescence 35% for 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 thin material minimizes awareness of the tray because it occupies less of the patient's interocclusal space. Scalloping and reservoirs further reduce pressure on the teeth and gums.

Pre-Treatment Procedure:
1. A diagnosis to ensure soft tissue health must precede a bleaching treatment. Address failed restorations and/or areas of caries. 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 external 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. 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 or cores 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 these teeth 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 is often caused by a temporary color shift from dehydration (and then rehydration) of the teeth. With difficult intrinsic stains, the thicker portions of the tooth usually lighten less (i.e., gingival third lightens less than the body and incisal thirds).
7. When not in use, trays should be stored in the appliance cases provided in each Opalescence kit.
8. Dark, nonvital, 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 nonvital teeth can whiten significantly in 1-4 days.
9. If the dentist anticipates the patient may swallow or aspirate the tray(s), treatment should be avoided.

Procedure:
1. Fabricate the tray using laboratory instructions, or send the working cast/model and 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 regimes to patient:
a. Most dentists prefer nighttime bleaching regimes 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, and Opalescence 35% for 30

minutes.
Note: Only Opalescence 10% (PF and non-PF) should be worn overnight.
b. Alternative, customized 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 reinitiated.
3. Show patient 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 soft brush and cool 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 may be 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, bland fluoride gel (Flor-Opal™). Daytime use insulates teeth from cold, allowing sensitivity to subside.
b. Appropriate administration of mild anti-inflammatory analgesics (e.g., ibuprofen or aspirin).
5. Evaluate patients every 3-5 days of treatment. The clinician may schedule checkups more or less frequently, depending on patients' needs and degrees of progress. The number of days required for complete treatment depends on the type of stains present and their severity. For example, tetracycline stains require more treatment time than other types of disfiguring 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.
4. If patient has a known allergy or chemical sensitivity to peroxides, carbopol, glycerin, etc., Opalescence is NOT to be used. Mint flavor can be irritating to some patients. If patient has a known sensitivity to mint, use alternate flavors.
5. 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, etc., or temporarily with dentin sealant.
6. 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.
7. 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.
8. If gingival or tooth discomfort persists (such as excessive temperature sensitivity), inform patient to remove tray, discontinue treatment and make an appointment for evaluation.
9. Maintain control of Opalescence whitening agent, dispensing only what is needed to reach the next evaluation appointment (approximately 3 to 5 days).
10. Monitor patients' bleaching progress to prevent bleaching beyond the desired level of whitening or degree of translucency.

11. Understand each patient's expectations before beginning treatment. Inform patients that existing crowns, tooth colored fillings, etc., do not whiten, even though natural teeth potentially will.
12. 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.
13. Material should be refrigerated to maintain shelf life. Instruct patients to keep Opalescence out of heat and/or direct sunlight.
14. Patients with heavy occlusion or bruxers may require a thicker tray. We recommend 0.60" tray material.
15. Avoid treatment if patient may swallow or aspirate tray.
16. Instruct patients to be careful not to swallow gel or rinsed gel. Opalescence tooth whitening products contain peroxide and may contain fluoride; 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. Note palate and tongue areas are removed. Allow model to dry two hours.
2. Ultradent™ LC Block-Out quickly provides reservoir spaces in tray. Apply -0.5mm thickness of material onto desired labial surfaces. Stay about 1.5mm from gingival line. DO NOT extend onto incisal edges and occlusal surfaces. This prevents margin of tray from opening upon biting and/or impinging on soft tissues. Patients may experience less tooth discomfort from tray pressures with reservoirs because of reduced orthodontic pressures. Cure LC Block-Out for approximately 2 minutes (Ultra-Lumes™). A hand-held intraoral light can be used (-20-40 seconds per tooth). Wipe off oxygen inhibition layer.
3. With vacuum former (UltraVac™ or use Econo Vacuum Former), heat tray material until it sags approximately 1 inch. Activate vacuum and adapt softened plastic onto model. Cool and remove model.
4. Cut excess bulk of material away with serrated plastic trimmers (Ultradent™ Utility Cutters).
5. With small tactile scissors (Ultra-Trim™ Scalloping Scissors), carefully and precisely trim tray 0.25 to 0.33mm occlusal from gingival margin. Scallop the gingival embrasures to prevent covering the gingival papillae with the tray. The papillae may become sore and irritated if tray covers them!
6. Return tray to model; check tray extensions. Gently flame polish edges, one quadrant at a time, with a butane torch.
7. While still warm, hold periphery of each segment firmly against model for three seconds with water-moistened finger. If an area is short of the desired length, gently hear 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 cool tap water. Store tray in appliance case when not in use.

Opalescence™
Tooth Whitening Systems

产品名称
牙齿美白胶

规格型号
Opalescence PF 10%、Opalescence PF 15%、Opalescence PF 20%。
包装规格：1.2mL/支

描述：
Opalescence是在牙科医生的控制和监护下由患者自行在家使用的单位剂量注射器包装的牙齿漂白系统。Opalescence漂白系统为无色、粘稠，10%、15%或20%浓度的过氧化脲凝胶(pH-6.5)。组成成分有过氧化脲、丙三醇、卡波姆、氢氧化钠、氟化钠和水。

适用范围：
本品用于16岁以上身体健康人群，因烟草、可乐、茶、咖啡、酱油等有色物质造成的外源性染色牙的牙齿美白。本品家庭自用，必须经过专业医生的专业指导，且应在医生的监督下定期诊疗。注意：因为口腔修复材料不能美白，所以我们建议充填修复材料之前美白暗色牙齿，这样可以使修复部分和经过美白后的底色更相配（在漂白进行两周后再填充修补材料）。

主要组成
主要组成成分：过氧化脲、丙三醇、卡波姆、氢氧化钠、氟化钠、水。产品为无色透明粘性胶体，带有气泡。有效成分过氧化脲的含量分别为10%、15%、20%。有无味、薄荷味和甜瓜味三种类型。

禁忌症
对组分中任一成分过敏者禁用。

警告和警示
无

使用步骤：
1. 将牙模和处方订单（附在套盒内）寄送到Ultradent。
2. 按使用说明对患者进行有关漂白步骤、清洗、Opalescence使用、以及托盘养护的指导。向患者说明治疗方式：
a. 多数牙医更希望他们的患者能在晚上美白牙齿以达到最佳效果。原因是睡觉期间唾液减少，需要的美白剂则随之减少。口腔内活动的减少则可避免漂白牙托内的美白剂的“流失”。佩戴时间Opalescence 10%为8-10小时或整夜，Opalescence 15%为4-6小时，Opalescence 20%为2-4小时。
注意：仅Opalescence 10%可以整夜佩戴。
b. 根据患者需求、敏感度和日常活动，患者每天可多次使用其它有针对性的治疗产品，但每次使用不应超过30分钟。
c. 停用几夜之后重新使用不会影响持续的漂白。
3. 为患者演示注满托盘的方法：将一股连续的胶体挤到从托盘正面对边向上大约一半（或稍低一点）的位置。所用的凝胶数量应该不超过过注射器容量的1/3到1/2。指导患者在每次使用后用软刷和冷水清洗托盘。
4. 有时牙齿的敏感症状和/或齿龈发炎需要医治。首选治疗方法是使用Ultra EZ™，一种成分为硝酸钾，性状粘稠的胶体，请将Ultra EZ®挤至Opalescence漂白牙托内佩戴，根据需要可使用12小时，也可整晚使用。
a. 患者还可佩戴挤有一种近似中性，粘稠，刺激性小的含氟胶体（FlorOpal™）的牙托。日间使用可以防止牙齿受冷，缓解敏感症状。
b. 适当应用平和的抗炎止痛药。（例如，布洛芬或阿司匹林）。
5. 正常情况每3到5天对患者的疗效进行检查。医生也可根据患者的需要和进展程度增加或减少预约检查的频率。完全治愈所需天数主要由牙齿变色类型和轻重程度而定。比如，四环素牙比其他有损容貌的牙齿变色所需治疗时间要长一些。

注意事项：
1. 使用推荐的托盘设计并采用合适的治疗方法以达到最佳的患者舒适度。

2. 在开始治疗前，牙龈和口腔整体健康状况应保持良好。
3. 安全起见，不应在怀孕期间使用Opalescence。
4. 如果已知患者对过氧化氢、丙三醇等过敏或有化学敏感症状，不应使用Opalescence。薄荷香味也可能使有些患者不适。如果已知患者对薄荷有敏感症状，应换一种口味。
5. 修复部分必须密封完毕，所有暴露的敏感牙本质也必须覆盖好。如有敏感症状史，应使用恰当的修复材料和牙本质粘合剂进行处理，或用牙本质密封胶进行临时治疗。
6. 有可能存在肉眼看不到的超级钙化区。超级钙化区会更快变白，所以在漂白过程中会更明显。继续治疗，直到没有钙化的牙齿表面与之混为一体。漂白治疗两周后，当牙齿颜色稳定之后重新评价效果。
7. 根据牙齿变色的轻重程度，每隔几天检查患者的进展情况。如果只想取得较小变化，在1到三天内评估患者的进展。因为有些牙齿经漂白会变得更透明，用大的金属填充物仔细观察，以防填充物透过牙齿显露出来。
8. 如果牙龈或牙齿不适持续不退（例如对温度过于敏感），让患者取下托盘，停止治疗，并预约时间检查敏感症状程度。
9. 控制Opalescence美白剂的用量，所配剂量应正好用到下次预约检查前（大约三至五天）。
10. 监视患者的美白过程，防止超出要求的美白程度或半透明的程度。
11. 在开始治疗前，要了解清楚每个患者的期望值。向患者告知虽然天生的牙齿有潜在的美白可能，现有的烤瓷牙，与牙齿同色的填充物等无法美白。
12. Opalescence美白剂采用1.2毫升单位剂量注射器包装。注射器内的材料不应作注射用，应对患者说明使用完后将注射器扔掉。
13. 应将材料保存至2℃-27℃以保持其寿命。指导患者将Opalescence避热和/或避光存放。
14. 有严重咬合问题的患者可能需要较厚的牙托。我们建议使用0.6毫米的托盘材料。
15. 如果患者有可能咽下或吸入牙托，应避免治疗。
16. 指导患者注意不要吞咽胶体或残渣。Opalescence牙齿美白产品含有过氧化氢，还可能含有氟；大量吞咽可能会有害。

储存与运输
牙齿美白胶应在2℃~27℃储存。牙齿美白胶为塑料注射器包装，外包装为纸盒包装。允许使用一般交通运输工具，但须防止运输过程中的剧烈冲击、震动及雨雪淋溅。

生产日期
见外标签

有效期：
24个月

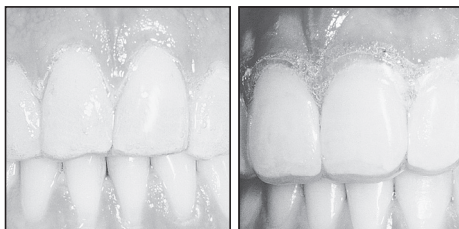
配件清单
无

注册人/生产企业
名称：Ultradent Products, Inc. 美国皓齿制品有限公司
住所/生产地址：505 West 10200 South, South Jordan UT 84095, USA
联系方式：电话：800.522.5512 传真：801.572.0600

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住所：广州市海珠区工业大道北路67号34号楼首层自编102房
联系方式：电话：020-84156506；传真：020-84156535

医疗器械注册证编号/产品技术要求编号：国械注进20183172676

说明书编制或者修订日期：
编制日期：2018年12月21日
修订日期：2019年09月07日



EN Stay shy of gingiva, scalloping around interdental papilla.
ZH 远离牙龈，齿间乳头处做弧线修剪。

EN Lapping onto gingiva may irritate tissues.
ZH 涂抹牙龈可导致软组织疼痛。

Opalescence PF 35% Regular

Ingredients: Glycerin, Water (aqua), Urea (Carbamide) Peroxide, Carbomer, Hydrogen Peroxide, PEG-300, Xylitol, Sodium Hydroxide, EDTA, Potassium Nitrate, Sodium Fluoride, Sucralose

Opalescence PF 35% Mint and Melon

Ingredients: Glycerin, Water (aqua), Urea (Carbamide) Peroxide, Carbomer, PEG 300, Hydrogen Peroxide, Xylitol, Sodium Hydroxide, Flavor (aroma), EDTA, Potassium Nitrate, Sodium Fluoride, Sucralose

Opalescence PF 20% Regular

Ingredients: Glycerin, Water (aqua), Urea (Carbamide) Peroxide, Xylitol, Carbomer, PEG-300, Sodium Hydroxide, EDTA, Potassium Nitrate, Sodium Fluoride

Opalescence PF 20% Mint and Melon

Ingredients: Glycerin, Water (aqua), Urea (Carbamide) Peroxide, Xylitol, Carbomer, PEG 300, Sodium Hydroxide, Flavor (aroma), EDTA, Potassium Nitrate, Sodium Fluoride

Opalescence PF 15% Regular

Ingredients: Glycerin, Water (aqua), Urea (Carbamide) Peroxide, Xylitol, Carbomer, PEG-300, Sodium Hydroxide, EDTA, Potassium Nitrate, Sodium Fluoride

Opalescence PF 15% Mint and Melon

Ingredients: Glycerin, Water (aqua), Urea (Carbamide) Peroxide, Xylitol, Carbomer, PEG 300, Sodium Hydroxide, Flavor (aroma), EDTA, Potassium Nitrate, Sodium Fluoride

Opalescence PF 10% Regular

Ingredients: Glycerin, Water (aqua), Xylitol, Urea (Carbamide) Peroxide, Carbomer, PEG-300, Sodium Hydroxide, EDTA, Potassium Nitrate, Sodium Fluoride

Opalescence PF 10% Mint and Melon

Ingredients: Glycerin, Water (aqua), Xylitol, Urea (Carbamide) Peroxide, Carbomer, PEG 300, Sodium Hydroxide, Flavor (aroma), EDTA, Potassium Nitrate, Sodium Fluoride

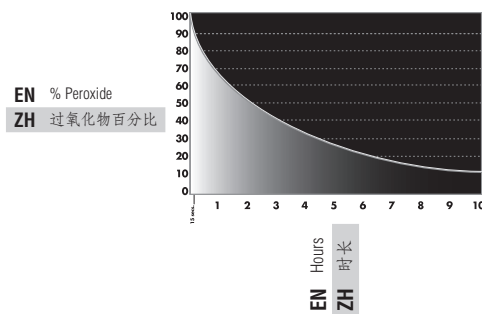
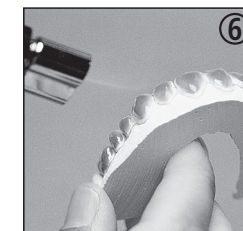
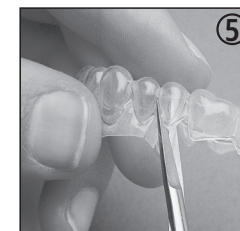
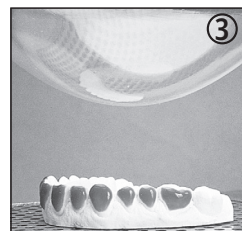
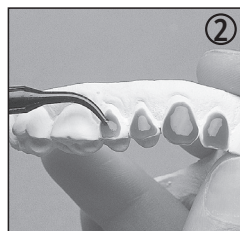
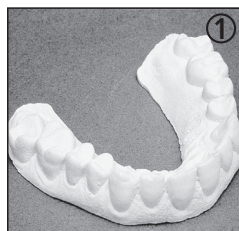


X026 = LOT
X026 = MM
X026 = YYYY

Ultradent syringes have an expiration date stamped on the side of the syringe consisting of one letter and three numbers. The letter is a lot number used for manufacturing purposes and the three numbers are the expiration date. The first two numbers are the month, and the third number is the last number of the year.

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.

Refrigerate to maintain shelf life.
All Opalescence Products are Gluten Free



EN Sustained Release Test: After dental examination and prophylaxis, 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.

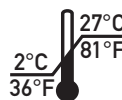
EN 持续释放测试：在经过口腔检查后，放入 Opalescence 为客户特别定制的牙托（塑料薄膜）。夜里会不定期取出少量的美白凝胶，以分析活性成分的百分比。



EN- Keep out of reach of children
ZH- 置于儿童不能触及之处



EN- Use by date
ZH- 有效期



EN - Required storage condition
ZH - 所需的储存条件



EN- Lot Number
ZH- 批号



EN- Catalog Number
ZH- 目录号



EN- For professional use only
ZH- 仅用于专业用途



EN- Keep away from heat/sunlight
ZH- 避免热源/日晒



EN- Recycle
ZH- 回收



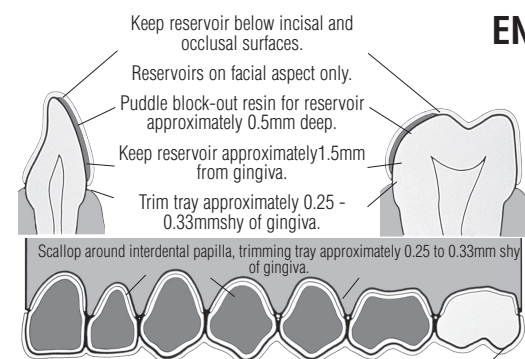
EN- Health hazard
ZH- 健康危害



EN- Consult instructions for use
ZH- 使用请参照说明

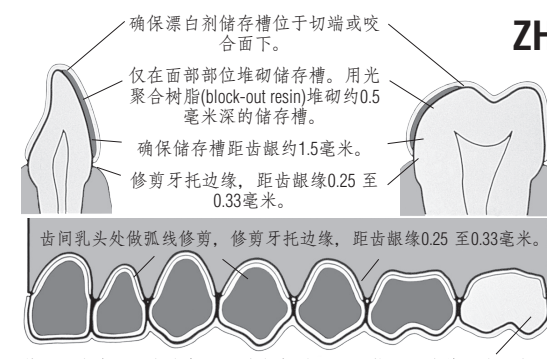


EN- 合格标识
ZH- 检验合格



EN If one or more teeth are much darker than others (e.g., overly dark cusps), build reservoirs on cusps only to balance end whitening results.

EN Teeth of lower esthetic concern need not receive resin.



EN 若一颗或多颗牙齿的色泽比别的暗（比如：过暗的尖牙），则在尖牙处堆砌储存槽，以协调最终的美白效果。

EN 较不影响美观的牙齿不需要树脂。

Opalescence[™]
tooth whitening systems



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