

Product FAQs:

➤ What is the Invisalign Professional Whitening System?

This is a professional tooth whitening system with the leading Opalescence PF whitening formula from Ultradent, optimized for use with Invisalign® clear aligners, Vivera™ retainers, and Invisalign whitening trays.

The system uses the co-branded name, 'Invisalign Professional Whitening System, powered by Opalescence' and offers the same great whitening outcomes and streamlined practice experience that dental professionals expect from Ultradent's Opalescence PF product. Now your patients can achieve whitening during active tooth movement with Invisalign aligners, as well as during passive retention using Vivera retainers.

This is the only professional teeth-whitening product approved by Align for combined use with Invisalign clear aligners or Vivera retainers.¹

➤ Which Invisalign Professional Whitening System product options are offered in the US?

In the US, there are two whitening products available: an at-home product and an in-office product.

Doctors or their team members can administer the in-office teeth-whitening treatment or instruct their patients to administer the at-home treatment. Both the in-office product and the at-home product are fully tray-based whitening systems where the whitening gel is delivered using an Invisalign clear aligner, a Vivera retainer, or an Invisalign whitening tray.

More details as follows:

a. At-home treatment

- (4) 3ml syringes with 10% carbamide peroxide whitening gel
- Recommended regimen of 14 overnight (8- to 10-hour) applications
- Use with Invisalign clear aligners, Vivera retainers, or Invisalign whitening trays
- No light, gingival barriers, cheek retractors, or specialized equipment is required

b. In-office treatment

- (1) 3ml syringe with 45% carbamide peroxide whitening gel to be administered in a single appointment with 3 consecutive 30-minute applications
- (1) 3ml syringe with 10% carbamide peroxide whitening gel for 3 overnight (8- to 10-hour) applications to be self-administered by the patient at home after the in-office portion is complete
- Use with Invisalign clear aligners, Vivera retainers, or Invisalign whitening trays
- No light, gingival barriers, cheek retractors, or specialized equipment is required

Customized Invisalign whitening trays are included as part of the stand-alone order option at no additional charge for patients receiving whitening-only treatment.

➤ What is the difference between the Ultradent Opalescence PF product and the Invisalign Professional Whitening System product?

The Invisalign Professional Whitening System was uniquely developed to be used with Invisalign clear aligners, Vivera retainers, and Invisalign whitening trays.

With an optimized viscosity, our whitening gel covers and remains in contact with tooth surfaces for the recommended overnight wear time and is designed specifically for tooth whitening use in Invisalign aligners.² The whitening gel is made up of at least 20% water, which can help reduce tooth dehydration.² (cont.)

Ultradent's Opalescence PF product is not approved by Align for use with Invisalign® clear aligners or Vivera™ retainers.

Customized Invisalign™ whitening trays are included at no additional cost as part of the stand-alone order option for patients not currently in Invisalign treatment or Vivera retainers.

➤ **What are the Invisalign whitening trays?**

The Invisalign whitening trays are included as part of the complete system free of charge for patients not in active treatment or retention. They are customized for each patient out of a transparent thermoplastic material. They are rigid yet elastic, so they are comfortable to wear and easy to apply. They are similar in design and fit to Invisalign clear aligners and Vivera retainers.

➤ **Does this system require a light or any other specialized equipment?**

No, the Invisalign Professional Whitening System comes with everything you need right out of the box. No light, gingival barriers, cheek retractors, or other specialized equipment is required to administer either the at-home or in-office options.

➤ **How long do teeth-whitening results last?**

Teeth whitening results are very stable, leaving patients with a stunning smile long after treatment is over. However, there are a few factors that can make teeth lose their luster. Things like tooth anatomy (deep grooves, thicker/thinner enamel, or rough surfaces), diet (red wine, coffee), age, and certain habits (like smoking) may affect the duration of whitening results.

➤ **Who has access to this whitening product?**

The Invisalign Professional Whitening System is available throughout the US to all Invisalign-trained doctors.

➤ **Where can doctors order the Invisalign Professional Whitening System?**

Align Technology is the only distributor of the Invisalign Professional Whitening System. Invisalign-trained doctors can order the Invisalign Professional Whitening System through the Invisalign Doctor Site.

Invisalign providers can order the whitening product as an add-on for patients using Invisalign clear aligners or Vivera retainers, or as a stand-alone for whitening-only patients who will use the Invisalign whitening trays.

For new Invisalign or Vivera patients, or for whitening-only patients, submit the order along with their prescription form. For current Invisalign or Vivera patients, simply order through the [WebStore](#) within the Invisalign Doctor Site.

➤ **How much does the system cost?**

The in-office product costs \$75. The price applies both to add-on orders for use in connection with patients in Invisalign treatment or Vivera retention, in which patients will use their Invisalign clear aligners or Vivera retainers to administer the whitening treatment, and to stand-alone orders for use in connection with whitening-only patients, in which Invisalign whitening trays are included at no additional charge.

The at-home product costs \$50 for an Invisalign treatment or Vivera retainer add-on order, as well as for the stand-alone order option that includes Invisalign whitening trays at no additional charge.

All prices are subject to change.

➤ **Can patients purchase the whitening product directly?**

No. The Invisalign™ Professional Whitening System is only available through the Invisalign® Doctor Site to Invisalign-trained doctors.

➤ **Can team members administer the whitening gel?**

The Invisalign Professional Whitening System can be easily administered by a team member, subject to compliance with any and all applicable state and federal laws, regulations, and professional codes of practice. Application training is available in the [Education Portal](#) within the Invisalign Doctor Site.

➤ **Does the Invisalign Professional Whitening System gel degrade the Invisalign clear aligner, Vivera™ retainer, or Invisalign whitening tray material?**

Both the at-home and in-office products were specially developed and thoroughly tested for use with Invisalign clear aligners and Vivera retainers.³ When used according to the label, the gel will not affect the integrity of the material comprising the Invisalign clear aligner, Vivera retainer, or Invisalign whitening tray.

➤ **Can Invisalign whitening trays be used as passive aligners or retainers?**

No, Invisalign whitening trays were not designed to move or retain teeth and should not be used as a replacement for Invisalign clear aligners, Invisalign retainers, or Vivera retainers.

➤ **What iTero™ scan type is used to order the Invisalign whitening trays?**

In the Order area, select the “Invisalign + iRecord” case type from the Case Type drop-down list.

➤ **Do the Invisalign whitening trays have wells or reservoirs?**

No, the Invisalign whitening trays do not have wells or reservoirs. In the design and development of the Invisalign Professional Whitening System, a variety of configurations and formulations were explored, and, ultimately, it was found this system works well even without reservoirs. The thin layer of gel gets distributed to cover the tooth surfaces due to the precise fit of the trays, and is sufficient to provide whitening.

➤ **Where can doctors learn more about the Invisalign Professional Whitening System?**

Check out our professional-facing website at: [Invisalign.com/WhiteningSystem](https://invisalign.com/WhiteningSystem).

For support and questions, email InvisalignProfessionalWhitening@aligntech.com and the Align™ customer support team will get back to you.

➤ **Are educational resources available to help train doctors and/or staff?**

Yes, a training module is available in the [Education Portal](#) within the Invisalign Doctor Site to assist with doctor and team training.

➤ **Are marketing resources available to help doctors promote the Invisalign Professional Whitening System?**

Yes, in-office marketing materials, including a table tent, poster, window decal, patient flyer, and social media assets designed for doctors to post on social media channels are available on the [Invisalign Marketing Site](#).

Clinical FAQs:

➤ **Can the patient be sent home with the 45% carbamide peroxide whitening gel to self-administer?**

No, the 45% carbamide peroxide whitening gel should be administered by a dental professional at the dental office.

The 10% carbamide peroxide may be self-administered by the patient with application instruction from a dental professional.

➤ **At what stage during the Invisalign® treatment process may I administer the Invisalign™ Professional Whitening System?**

The Invisalign Professional Whitening System can be applied at any point during treatment. Integration into treatment planning is easy and, where appropriate, can be applied up-front during patients' initial consultation to help generate excitement about their Invisalign therapy journey. The Invisalign Professional Whitening System can be administered after attachments have already been bonded.⁴

➤ **Can the doctor use desensitizing products prior to administering the Invisalign Professional Whitening System?**

Yes. While the Invisalign Professional Whitening System is formulated with potassium nitrate and fluoride, the clinician may choose to administer a desensitizing regimen (such as a desensitizing gel, sensitivity relief toothpaste, and/or fluoride varnish) prior to, during, or after administering professional whitening.

➤ **Can the clinician install a gingival barrier when administering the 45% carbamide peroxide regimen of the in-office product?**

No, a gingival barrier is contra-indicated for the Invisalign Professional Whitening System as there is an increased risk of the Invisalign clear aligner, Vivera™ retainer, or Invisalign whitening tray dislodging the barrier and allowing whitening gel to get trapped under the barrier.

We recommend that when administering the 45% carbamide peroxide regimen of the in-office product, clinicians consider the following best practices:

- Do not overfill whitening gel inside of the Invisalign clear aligner, Vivera retainer, or Invisalign whitening tray.
- Pay close attention when seating the tray in the patient's mouth and promptly remove any gel that may extrude through the top of the tray and come in contact with the gingiva.
- After seating the tray in the patient's mouth, run gauze, tissue, or a cotton roll along the edges of the tray to remove any gel that may be in contact with the gingiva; have the patient rinse with water and spit. Please note there will still be sufficient gel between the trays and the teeth even after rinsing.
- Check in with the patient shortly applying the whitening treatment; if the patient experiences any irritation or tingling, clean any gel from the gingiva. If the patient still experiences discomfort, discontinue treatment, rinse the mouth, and clean teeth thoroughly.

➤ **How can the clinician or patient mitigate contact of the whitening gel with interproximal papilla that may be partially covered by the Invisalign® clear aligner, Vivera™ retainer, or Invisalign™ whitening tray?**

One way to mitigate contact between the whitening gel and interproximal papilla is to cover the gingiva with a light coating of petroleum jelly prior to applying the whitening treatment in the patient's mouth.

➤ **Is it normal to observe some redness or white spots on the gingiva after applying the in-office regimen?**

Yes, some patients may experience minor gingival irritation after the whitening gel is administered. Redness, white spots, or sloughing may be observed in isolated areas on the patient's gingiva if the whitening gel was in contact with the gingiva for an extended period. Gingival irritation from contact with the whitening gel is temporary and will go away by itself often within 24 hours.

➤ **For current Invisalign patients, does the solution whiten under attachments?**

The Invisalign Professional Whitening System contains the active whitening ingredient carbamide peroxide. Peroxide gels break down into water, oxygen, and reactive oxygen molecules. These reactive oxygen molecules treat both the enamel and the dentin, oxidizing the bonds of discolored stain molecules. By changing the stained molecules, the tooth color becomes lighter.⁵ Reactive oxygen molecules formed during the whitening process permeate the entire tooth, so there is no need for the whitening agent to be in contact with every surface of the tooth to be whitened. The Invisalign Professional Whitening System can be administered after attachments have already been bonded.⁴

➤ **Are there any dental conditions that can affect the success of tooth whitening?**

Yes. All decay and other urgent dental work should be treated prior to beginning any whitening procedure. It is safe to whiten teeth with fluorosis (hypocalcified white spot lesions), but patients should be notified prior to treatment that the areas will whiten faster and become more noticeable immediately following whitening. As teeth gradually rehydrate, it will not be as noticeable. Teeth that have had root canal treatment will not whiten as much as vital teeth. Teeth with tetracycline staining will not whiten as well.

¹Data on file at Align Technology, as of July 31, 2021.

²Data on file at Align Technology, as of July 11, 2022.

³Data on file at Align Technology, as of July 31, 2021.

⁴It is the doctor's responsibility to administer in accordance with the IFU.

⁵Kwon SR, Wertz PW. Review of the Mechanism of Tooth Whitening. J Esthet Restor Dent. 2015 Sep-Oct;27(5):240-57.