

## Five Facts To Know About Clear Aligner Therapy

Clear aligner therapy has revolutionized orthodontic treatment and has been embraced by practitioners and patients around the world – a revolution made possible by digital technology and newer materials<sup>1</sup> that are simultaneously rigid enough to move teeth, but still flexible enough to be comfortably and easily inserted and removed from a patient’s mouth.

Information about clear aligner therapy can be obtained from many sources, not all of which accurately convey important facts that patients and potential patients should know about this orthodontic treatment option. As the category creator and continuous technological innovator, Align Technology takes pride in supporting dental health professionals to help drive progress in dental practice and provide relevant information on clear aligner therapy so patients can make more informed decisions regarding their treatments. Align markets its products and services to licensed dentists or orthodontists and has never sold directly to consumers or patients.

### **1. Moving teeth – even if the goal is only improved appearance – is a medical treatment**

Orthodontic treatment – even simple tooth movement – is medical treatment that moves teeth through the bone of the jaw.

Some patients are not good candidates for orthodontic treatment including clear aligner therapy. They may have cavities or underlying conditions such as periodontal disease that must be assessed and resolved before treatment can safely take place. Only an in-person exam by a licensed dentist can make this determination.

If not properly supervised and monitored, ‘simple’ treatment may improve a patient’s smile but simultaneously create potentially serious dental problems (even tooth loss)<sup>2</sup> that have long term health implications.

### **2. Clear aligners are medical devices in the same classification as brackets and wires**

Just like brackets and wires, clear aligners are medical devices and treatment must be planned and regularly monitored by a doctor. The Invisalign System is a Class IIa medical device cleared by both the U.S. Food and Drug Administration and the Australian Therapeutic Goods Administration. In the European Union, the Invisalign System and Vivera Retainers are designated as a Class IIa medical device, both bearing the CE mark and the 0344 Notified Body number of DEKRA certification, CE 0344.

Treatment using the Invisalign system with attachments and other special features enables doctors to effectively treat all classes of malocclusions (including more complex Class II and dental class III malocclusions including tooth extractions).

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<sup>1</sup> Invisalign clear aligner’s patented multi-layer aligner material, SmartTrack is the result of almost 8 years of development and testing 260 different materials

<sup>2</sup> Without in-person evaluation of a patient’s mouth, gums, teeth and underlying structures by a licensed dentist before treatment begins, careful treatment planning and regular oversight, orthodontic treatment can cause changes in dentition that may harm patients -- negatively affect the bite or soft tissues, or even cause loss of tooth vitality (compromised blood flow that can eventually lead to tooth loss).

### **3. The Invisalign system can provide effective treatment for a broad range of conditions and a wide range of patient age groups**

The product of more than two decades of innovation, Align's Invisalign system is the most advanced clear aligner system in the world – able to address a broad range of orthodontic case complexity (including bite corrections and functional changes) and treat approximately 90% of patient cases for adults, adolescents and children as young as 6 years old.<sup>3</sup>

Clear aligner treatment for younger patients like Invisalign First and Invisalign Teen can address necessary functional corrections of the teeth, jaws and arches. Designed specifically for patients with a mix of primary and permanent teeth, these treatments address challenges such as correcting positioning of the upper and lower teeth and providing predictable arch expansion.<sup>4</sup>

### **4. Patients should have a thorough clinical examination before undertaking any orthodontic treatment including clear aligner therapy**

Physical impressions that accurately reflect a patient's dentition (teeth and fit of upper and lower jaws) are hard to take, even by a trained professional in a dentist's office, and often have to be repeated. And even when the impression is acceptable, it is not as accurate as an intraoral scan. Intraoral scans capture hundreds of thousands of digital data points to create a precise 3D digital image of a patient's teeth.

Because they can accurately capture details of virtually every tooth surface, intraoral scans should be considered the method of choice (versus traditional alginate, or 'putty' oral impressions) for creating clear aligners and clear aligner treatment plans and making well-fitting appliances such as crowns, bridges or dental implants.

All orthodontic treatment, including clear aligner therapy moves a patient's teeth through the bone of their jaw, so before treatment, a licensed doctor must review the patient's most recent radiographs (XRays) or other equivalent bone imaging studies to clearly visualize the patient's teeth in the bone of the jaw. Digital scans alone cannot provide data structures below the gumline.

### **5. Clear aligner therapy requires continuous direct doctor supervision**

When used responsibly by trained, licensed dental healthcare providers, digital technologies and tools including remote doctor-patient consultation (teledentistry) have enormous potential to extend professional care and enhance both patient outcomes and convenience. However, orthodontic treatment is a complex discipline that involves the movement of a patient's teeth through bone. It is essential that trained orthodontists and/or dentists are directly involved in patient assessment and diagnosis (including evaluating the patient in an initial, in-person office visit), treatment planning, prescription and fitting of clear aligners and ongoing monitoring of the patient through treatment. This oversight is particularly relevant to clear aligner treatment because with removable appliances, the monitoring of patient compliance with the required daily wear time of their aligners is essential to achieve the desired outcome.

#### **Important Facts About Align Technology**

- >10.9 million patients have been treated with the Invisalign system -- >2 million in EMEA
- ~2.8M of these are teens and younger patients.

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<sup>3</sup> Q1 Earnings, April 28, 2021

<sup>4</sup> Invisalign First Clear Aligners [<https://www.invisalign.com/the-invisalign-difference/invisalign-first>]

- >200,000 doctors had been Invisalign trained worldwide<sup>3</sup>
- Align has *invested >\$2 billion in technological innovation<sup>5</sup> since its inception -- more than \$1 billion since 2010 alone.*
- In 2021 Align expects its annual R&D spending to reach \$250 million.<sup>3</sup>
- Align holds over 1,267 active patents – roughly half U.S. and half foreign patents -- and has 650 pending patent applications worldwide.

### **About Align**

Align Technology is a global medical device company that designs, manufactures, and markets *the Invisalign system*, the most advanced clear aligner system in the world, and *iTero intra-oral scanners and services*

### **Company Owned Marks**

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