



## Align Technology Receives US FDA 510(k) Clearance for the Invisalign® Palatal Expander System to Address Skeletal and Dental Expansion in Growing Patients, Including Teenage Patients Which Represent the Majority of Orthodontic Case Starts Globally

December 18, 2023

- **Invisalign® Palatal Expanders offer doctors a removeable, safe, and clinically effective alternative to traditional palatal expanders.**
- **Combined with Invisalign First™ aligners, Invisalign Palatal Expanders provide doctors with a full early intervention treatment solution, including both skeletal (orthopedic) and dental (orthodontic) arch expansion.**

SAN JOSE, Calif. & TEMPE, Ariz.--(BUSINESS WIRE)--Dec. 18, 2023-- Align Technology, Inc. ("Align") (Nasdaq: ALGN), a leading global medical device company that designs, manufactures, and sells the Invisalign® System of clear aligners, iTero™ intraoral scanners, and exocad™ CAD/CAM software for digital orthodontics and restorative dentistry, today announced that the U.S. Food and Drug Administration (FDA) has cleared Align's Invisalign® Palatal Expander System\* for commercial availability in the U.S. The FDA 510(k) clearance is for broad patient applicability, including growing children, teens, and adults (with surgery or other techniques).

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20231218813291/en/>



A young patient independently inserting Invisalign® Palatal Expander- courtesy of Dr. David Walt, Vaughan, Ontario, Canada

Previously introduced at the Align Technology Investor Day in September 2023, the Invisalign Palatal Expander System is a modern and innovative direct 3D printed device based on proprietary and patented technology. Invisalign Palatal Expanders are intended for use in rapid expansion and subsequent holding of skeletal and/or dental narrow maxilla (upper jaw) with primary, mixed, or permanent dentition during treatment of patients. The Invisalign Palatal Expander is Align's first direct 3D printed orthodontic device and provides a safe, comfortable, and clinically effective\* alternative to traditional palatal expanders that require manually turning a screw in the device in the mouth daily to achieve expansion.

Speaking at the company's 2023 Investor Day in Las Vegas, Srinu Kaza, Align senior vice president of product research & development said, "I am very proud to unveil the Invisalign Palatal Expander

System, our latest innovation in digital orthodontics based on proprietary and patented technology that builds on many industry firsts designed for treatment of children and teens, including Invisalign treatment with Mandibular Advancement and Invisalign First aligners. It is extremely rewarding for our team of engineers and material scientists to produce Align's first directly fabricated orthodontic appliance and pave the way for future innovation using direct 3D printing technology that enables more sustainable and efficient solutions."

The Invisalign Palatal Expanders consists of a series of removable devices staged in small increments of movement to expand a patient's narrow maxilla to a position determined by their treating doctor.\*\* Each direct 3D printed device is customized to the patient's unique anatomy based on an iTero™ intraoral digital scan. A palatal expansion treatment plan and device design are then developed using Align's proprietary AI-driven orthodontic software.

Combined with Invisalign First™ aligners, Invisalign Palatal Expanders provide doctors with a full early intervention treatment solution for Phase 1 treatment, an early interceptive orthodontic treatment for young patients. Phase 1 treatment is traditionally done through arch expanders or partial metal braces, before all permanent teeth have erupted – typically at ages 6 through 10. Invisalign First clear aligners are designed specifically to address a broad range of younger patients' malocclusions, including shorter clinical crowns, management of erupting dentition, and predictable dental arch expansion\*\*\*.

"The Invisalign® Palatal Expander System worked very well clinically, we had fewer emergencies and less chair time than we did with traditional expanders," said Dr. Don Spillers, an orthodontist in Warner Robins, Georgia and participant in an Invisalign Palatal Expander clinical trial. "The experience has definitely been much better for my patients with the Invisalign Palatal Expander System, as there was no cementing of bands, no fitting of a metal expander, and no screw to turn. All of the parents were happy and their kids were cooperative."

“Phase 1 or early interceptive treatment makes up 20 percent of orthodontic case starts each year and is growing,” said Dr. Mitra Derakhshan, Align senior vice president, Global Clinical. “Together with Invisalign First aligners, Invisalign Palatal Expanders provide doctors with a solution set to treat the most common skeletal and dental malocclusions in growing children. The addition of mandibular advancement features to Invisalign aligners also provides doctors with more options for treating skeletal and dental jaw imbalances and bite correction for their growing patients during their teenage years.”

The Invisalign Palatal Expander System is available on a limited basis in Canada and the U.S. It is expected to be available in other markets pending regulatory approvals starting in 2024.

*\*Based on a survey in August 2023 in Canada of 10 Invisalign trained orthodontists who participated in the Invisalign Palatal Expander System Technical Design Assessment and have treated at least 1 patient age 6-11 years with IPE. Data on file at Align Technology, Inc. as of October 30, 2023.*

*\*\*Based on data from a multi-site US IDE (Investigational Device Exemption) clinical study (n=29 subjects, ages 7-10 years) of expansion treatment with Invisalign® Palatal Expanders. Data on file at Align Technology, Inc. as of October 30, 2023*

*\*\*\*Data on File at Align Technology, Inc. as of June 2021.*

### **About Align Technology, Inc.**

Align Technology designs and manufactures the Invisalign® System, the most advanced clear aligner system in the world, iTero™ intraoral scanners and services, and exocad™ CAD/CAM software. These technology building blocks enable enhanced digital orthodontic and restorative workflows to improve patient outcomes and practice efficiencies for approximately 252 thousand doctor customers and are key to accessing Align's 600 million consumer market opportunity worldwide. Over the past 26 years, Align has helped doctors treat over 16.4 million patients with the Invisalign System and is driving the evolution in digital dentistry through the Align Digital Platform™, our integrated suite of unique, proprietary technologies and services delivered as a seamless, end-to-end solution for patients and consumers, orthodontists and GP dentists, and lab/partners. Visit [www.aligntech.com](http://www.aligntech.com) for more information.

For additional information about the Invisalign System or to find an Invisalign doctor in your area, please visit [www.invisalign.com](http://www.invisalign.com). For additional information about the iTero digital scanning system, please visit [www.itero.com](http://www.itero.com). For additional information about exocad dental CAD/CAM offerings and a list of exocad reseller partners, please visit [www.exocad.com](http://www.exocad.com).

Invisalign, iTero, exocad, Align, and Align Digital Platform are trademarks of Align Technology, Inc.

### **About the Invisalign Palatal Expander System\***

The Invisalign Palatal Expander System\* is a modern, innovative direct 3D printed orthodontic appliance designed based on proprietary and patented technology. The Invisalign Palatal Expander System is indicated for the orthodontic treatment of malocclusion. The system is used for the rapid expansion and subsequent holding of skeletal and/or dental narrow maxilla (upper jaw, dental arch and teeth, palate) with primary, mixed, or permanent dentition during orthodontic or orthopedic treatment in children or adolescents. In adults, it is to be used in conjunction with surgery or other interventions when necessary. . Devices are 3D printed and are manufactured based on digital scan data from commercially available iTero® intraoral scanners offered by Align Technology, Ltd. The devices are removable and more hygienic than traditional appliances; manufactured to custom fit each patient's anatomy for optimal comfort and aesthetics, expanders fit comfortably in the patient's mouth and changed daily (no screw required).

The System is comprised of Invisalign Palatal Expanders (active expansion, each stage comes with a programmed expansion of up to 0.25mm/stage, changed daily or as per doctor's discretion) and Invisalign Palatal Holders (copies of the last stage of the expansion phase designed to hold the maxilla post-active expansion and changed every 2-4 weeks as directed by the treating doctor), Invisalign Attachment Templates and proprietary 3D shape generation software.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20231218813291/en/): <https://www.businesswire.com/news/home/20231218813291/en/>

Align Technology, Inc.  
Madelyn Valente  
(909) 833-5839  
[mvalente@aligntech.com](mailto:mvalente@aligntech.com)

Zeno Group  
Sarah Johnson  
(828) 551-4201  
[sarah.johnson@zenogroup.com](mailto:sarah.johnson@zenogroup.com)

Source: Align Technology, Inc.