



## Align Technology Introduces the Invisalign® Palatal Expander System to Address Skeletal Expansion in Growing Patients, Including Teenage Patients Which Represent the Majority of Orthodontic Case Starts Globally

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- **Invisalign® Palatal Expanders offer doctors a removeable, safe, and clinically effective alternative to metal palate 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.**

TORONTO & LAS VEGAS & SAN JOSE, Calif. & TEMPE, Ariz.--(BUSINESS WIRE)--Sep. 6, 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 introduced the Invisalign® Palatal Expander System,\* a modern and innovative direct 3D printed device based on a 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 growing patients. The Invisalign Palatal Expander is Align's first direct 3D printed orthodontic device and provides a safe, comfortable, and clinically effective\*\* alternative to metal palatal expanders that require manually turning a screw in the device in the mouth daily to achieve expansion.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20230906445005/en/>



Dr. Sandra Tai's patient independently inserting Invisalign® Palatal Expander. (Photo: Business Wire)

Speaking from 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 Expander System 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™ digital scan. A palatal expansion treatment plan and device design are then developed using Align's proprietary AI-driven orthodontic software.

Phase 1 treatment is early interceptive orthodontic treatment for young patients, 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.

"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 a game changer, as it alleviates the most common challenges with palatal expansion, including maintaining proper hygiene, emergency appointments, turning the screw, and the parent's fear of causing pain to the child in treatment," said Dr. Sandra Tai, an orthodontist in Vancouver, Canada and participant in Align's Invisalign Palatal Expander System limited release program. "It's removable and supports oral hygiene while delivering a clinically effective and comfortable treatment experience for growing patients that achieves high satisfaction rates reported by parents."

The Invisalign Palatal Expander System is currently available on a limited basis in Canada (excluding Quebec) and is expected to be available in other markets pending regulatory approvals starting in 2024.

The Invisalign Palatal Expander System is pending pre-market notification (510(k) submission) to the U.S. Food and Drug Administration and is not yet available in the United States.

\*Data on file, Align Technology, as of August 2023.

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Based on data from a multi-site US Early Feasibility Investigational Device Exemption (IDE) clinical study (n=29 subjects, ages 7-10 years) of expansion treatment with Invisalign® Palatal Expanders.

## **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 247 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 15.7 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).

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

Invisalign Palatal Expander System\* is a modern, innovative direct 3D printed orthodontic appliance designed 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, dental arch, palate) with primary, mixed (primary and permanent), or permanent dentition during interceptive treatment such as Phase 1 treatment and orthodontic or orthopedic treatment in children or adolescents. 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 0.25mm/day) and Invisalign Palatal Holders (holders, changed every 2-4 weeks).*

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Align Technology  
Madelyn Valente  
(408) 470-1180  
[mvalente@aligntech.com](mailto:mvalente@aligntech.com)

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

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