Invisalign® Palatal Expander System by Align Technology Now Available in Turkey for Skeletal and Dental Expansion in Growing Patients

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

ROTKREUZ, Switzerland--(BUSINESS WIRE)--Feb. 10, 2025-- 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 Align's Invisalign Palatal Expander System has been approved by the Turkish Medicines and Medical Device Agency (TMMDA) and is now commercially available in Turkey. The approval is for broad patient applicability, including growing children, teens, and adults (with surgery or other techniques).

This approval marks another significant milestone in Align’s efforts to enhance clinical outcomes and efficiency in orthodontics.

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.

Simon Beard, Align Technology's executive vice president and managing director, Europe, Middle East, and Africa (EMEA), stated, "The Invisalign Palatal Expander System exemplifies Align's ongoing dedication to pioneering digital orthodontics. It offers enhanced efficiency for doctors and improved treatment experiences for young patients. We are excited to make this innovative 3D printed alternative to traditional palatal expanders available to even more doctors and their patients across the EMEA region."

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™ intraoral digital scan. A palatal expansion treatment plan and device design are then developed using Align’s proprietary orthodontic software.

With Invisalign First™ aligners and Invisalign Palatal Expanders,Align Technology can 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.

“Phase 1 or early interceptive treatment accounts for 20 percent of orthodontic case starts each year and is growing,” said Dr. Mitra Derakhshan, Align Technology executive vice president, chief clinical officer. “Together with Invisalign First aligners, Invisalign Palatal Expanders enables Align Technology to 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.”

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 over 271.6 thousand doctor customers and are key to accessing Align’s 600 million consumer market opportunity worldwide. Over the past 27 years, Align has helped doctors treat approximately 19.5 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 for more information.

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

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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 intended 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 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 for better oral hygiene[1]; manufactured to custom fit each patient's anatomy for optimal comfort and aesthetics, expanders fit comfortably in the patient's mouth and are 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. These products are not available for purchase by the general public. However, the products are available for purchase from Invisalign® trained dentists and orthodontists.

The Invisalign Palatal Expander System is currently available in the U.S., Canada, Australia, New Zealand, Hong Kong, Singapore, EU, UK, UAE, CH and Turkey, and is expected to be available in additional markets, pending regulatory approvals.

[1]Based on the survey in August 2023 in CAN 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, who responded to the question: "Please indicate your agreement with the following statement: Patients treated with the Invisalign® Palatal Expander System experience better oral hygiene than those patients treated with traditional palatal expanders (such as Schwartz, Hyrax, etc.)". Agreement scale is 1-4 with 1 being "strongly disagree" and 4 being "strongly agree". Data on file at Align Technology, as of October 30, 2023.

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