



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

April 1, 2024

- Invisalign® Palatal Expanders offer doctors an effective and easily removable alternative to traditional palatal expanders, without the need for metal and screws.
- 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.

SYDNEY--(BUSINESS WIRE)--Apr. 1, 2024-- 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 included in the Australian Register of Therapeutic Goods (ARTG) and the New Zealand Web Assisted Notification of Devices Database (WAND), and is commercially available in both Australia and New Zealand. The ARTG and WAND entries for Invisalign Palatal Expander System cover broad patient applicability, including growing children, teens and adults (with surgery or other techniques).

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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 an example of our continuous commitment to innovation by advancing digital orthodontics and delivering products with greater efficiency for doctors and provide better treatment experiences for patients and their parents," said Raj Pudipeddi, Align Technology chief marketing officer, executive vice president and managing director, Asia Pacific. "We are delighted to introduce the Invisalign Palatal Expander system, Align's first directly fabricated orthodontic appliance, to the Asia Pacific region."

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

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 customised 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*.

"Phase 1 or early interceptive treatment makes up 20 percent of orthodontic case starts each year and is growing," said Dr. Mitra Derakhshan, Align Technology 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."

"We are excited to present the Invisalign Palatal Expander system, a significant advancement in the field of digital orthodontics, to our doctor customers in Australia and New Zealand," said Jonathan Primmer, Align Technology vice president and managing director for Australia and New

Zealand. "With the increasing demand for orthodontic treatment among children and teenagers in Australia and New Zealand, the launch of the Invisalign Palatal Expander system allows us to offer a more comprehensive early interceptive treatment solution in conjunction with Invisalign First™, alleviating the most complex challenges with palatal expansion while providing an exceptional patient experience that is both comfortable and supports proper oral hygiene."

The Invisalign Palatal Expander System is now available in Australia and New Zealand. It is expected to be available in other APAC markets pending regulatory approvals starting in 2024.

**Data on File at Align Technology, 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 over 256 thousand doctor customers worldwide and are key to accessing Align's 600 million consumer market opportunity worldwide. Over the past 26 years, Align has helped doctors treat over 17 million patients worldwide 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.au. For additional information about the iTero digital scanning system, please visit www.itero.com.au. 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. 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, adolescents or adults 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 make it easier for patients to maintain oral hygiene compared to traditional palatal appliances; 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 0.25mm/day, changed daily or as per doctor's discretion) and Invisalign Palatal Holders (copy of the last stage of the expansion designed to hold the maxilla post-active expansion phase, 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.

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