

Invisalign® Palatal Expander System treatment guide

Tips and tricks for ultimate doctor, team, and patient success

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A note before getting started

Doctor,

Thank you for choosing the Invisalign[®] Palatal Expander System for your patients' treatment.

The Invisalign® Palatal Expander System is indicated for the orthodontic treatment of malocclusion. The system is used for 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. For adults, it can be used in conjunction with surgery or other interventions when necessary.

This guide is filled with peer-approved tips and tricks to help doctors and teams navigate this revolutionary treatment solution across the patient journey, from first consultation to final desired clinical outcome.

Best regards,

Align Technology

Visit the
Invisalign
Doctor Site
to access
the complete
Invisalign Palatal
Expander System
e-learning plan,
archived webinars,
whitepapers,
and more.



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Case selection



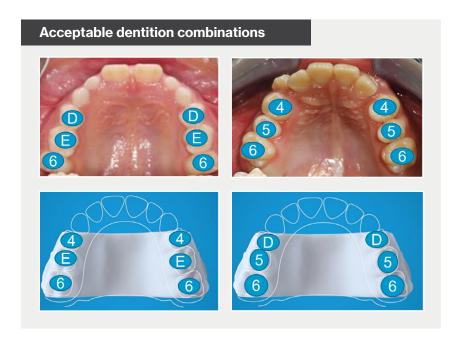
O1 Check the patient's teeth.

Are at least 3 posterior teeth present in each quadrant?

4/D Right Left5/E Right Left6 Right Left

Are all these teeth stable? (Teeth cannot be mobile, or the appliance may not fit during treatment)

Is there 4mm of crown height for each tooth? (If not, there is not enough space to bond an attachment on that tooth)



Note: Insufficient device retention, excessive force on dental restorations, and/or difficulty in attachment bonding may occur on teeth with stainless steel crowns or other types of dental restoration. Patients with stainless steel crowns might be eligible for treatment per doctor's discretion (note that the Invisalign First Palatal Expander device will cover these teeth).



Check the patient's palate, and health of soft and hard tissues.

Patient does not have active periodontal disease, caries, or hereditary angioedema.

Note: Invisalign Palatal Expanders require attachment to teeth for retention and help prevent tipping.

If your patient meets the above criteria, the patient is a great candidate for Invisalign Palatal Expanders. Proceed to scan according to the outlined protocol.

If not, the patient may not qualify right now – wait for teeth to erupt or exfoliate prior to proceeding.

Scanning protocol



Based on current business process applicability, Align Technology, Inc. currently accepts Invisalign[®] Palatal Expander System scans using commercially available iTero™ digital intraoral scanners only (offered by Align Technology, Ltd.). No 3rd party scans / PVS impressions are accepted. Please refer to iTero scanner user manual for complete instructions for use.

- Perform prophylaxis of the patient's teeth to remove plaque around gumline to expose as much of the surface area of the tooth crown as possible. Ensure the teeth and soft tissues are adequately rinsed and dried.
- 2. On the scanner, select **Invisalign | Vivera** procedure and **Invisalign Palatal Expander** procedure type.
- 3. Conduct a mandibular arch scan (scanning both arches is required to submit the Rx).

- 4. Conduct a maxillary arch scan to capture the gingiva, crown, and palate requirements:
 - a. Gingiva
 - i. Scan at least 3mm of gingival tissue beyond the clinical crown.

b. Crown:

i. Scan all crowns of the teeth completely. See above case selection checklist.

c. Palate:

- i. Scan the palate by starting in the incisive papilla and scanning straight down the center of the palate, following the midline towards the soft palate, ensuring the area of the hard palate between the distal of the terminal molars is captured.
- ii. Fill in the voids by returning to the incisive papilla area.
- iii. The palatal scan should be captured up to a line connecting the distal surfaces of the upper first permanent molars or terminal molars.
- 5. Once both arches are complete, proceed with a bite scan with both arches in occlusion.
- 6. Contact iTero clinical support at 800-577-8767 for a real-time scan and dental applicability quality check. Support will prompt you to press the 'help' button on your scanner to enable TeamView credentials and live instruction.

Note: If you would like to measure arch width, this is the time to do it. Measure the inter-molar distance for both arches to help you plan the desired expansion.

Watch: Scanning patients with iTero™ scanners instruction video

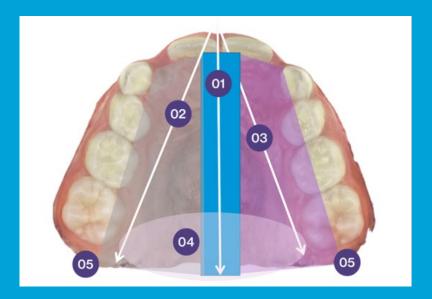




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Scanning strategy

The key for a successful palatal scan starts at the midline.



Pro Tip: Scan 2mm down past the line distal to the terminal molars on one side of the palate*. Repeat, scanning 2mm down toward the line distal to the terminal molar on the other side of the palate.

Scanning success checklist

No visible voids from an occlusal view along the palate's center between the distal molars.

The incisal edges are solid and free of voids.

Distal molars are completely captured.

3-4 mm of gingiva is visible around areas of 6s.

Both maxillary and mandibular arches are scanned.

The bite scan has been captured.

Pro Tip: If any part of the palate was removed while reviewing the model, disable the A.l. cleanup feature to bring back any of the trimmed soft tissue on the palate and buccal areas (it is not recommended to complete the entire scan with this feature disabled.)

Visit iTero Customer Learning Center - Editing tools for more information on how to enable/disable the A.I. Cleanup feature





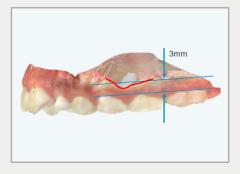
Examples of rejected scans for Invisalign Palatal Expanders



 Case not applicable for Invisalign Palatal Expanders due to missing dentition.



2. Scan does not meet acceptable criteria due to visible voids in palate.



 Scan does not meet acceptable criteria due to
 3 mm gingiva capture.

How do I know how much to expand?

The expansion amount for Invisalign Palatal Expanders is at the discretion of the doctor. However, here are some possible ways to help you make that decision:

- Option 1: Measure clinically in the patient's mouth.
 - For example, measure the maxillary and mandibular intermolar widths. Use the difference to help determine the expansion desired.
- **○** Option 2: Submit an Invisalign First[™] treatment ClinCheck[®] to measure on the digital model.
 - This option is particularly helpful when you plan to treat the mandibular arch simultaneously during expansion. You can use the arch width table to help assess the expansion you would like to plan for your patient.
- Option 3: Use OrthoCAD* to measure on the digital model.
- Option 4: Measure intermolar widths from a CBCT scan.
- Option 5: Use a standardized protocol, at your discretion.

For example, calculate your desired expansion from your clinical measurements. Each Invisalign Palatal Expander stage represents 0.25 mm of expansion:

 For 28 stages, this is equal to 7 mm of expansion. You may choose to add additional expansion, for example 1 mm additional expansion, and decide how many stages the patient will wear with monitoring.

*The values identified with these procedures are not meant to be used for research or diagnostics and should only be considered as reference material to observe a difference in arch width pre and post Invisalign Palatal Expander treatment and not as a clinical validation. Only available on PC. MAC is not supported.

Tips for ordering expanders



Invisalign Palatal Expander only workflow

- 1. On the Invisalign Doctor Site (IDS), select the appropriate patient age group
- 2. Select Invisalign Palatal Expander System
- Designate the amount of expansion desired and approve.
 Note: the current ordering protocol includes immediate approval when ordering as no ClinCheck[®] visualization is currently available.

Invisalign Palatal Expander and Invisalign First[™] treatment workflow

Currently, simultaneous treatment with Invisalign Palatal Expanders and Invisalign First treatment requires two patient IDs and two prescription submissions.

If you plan to move mandibular teeth, or if you want to visualize the case fully, submit an Invisalign First™ case, using the ClinCheck® to evaluate desired expansion. Then submit the Invisalign Palatal Expander prescription separately.

- 1. Complete the Invisalign First treatment ordering process
 - Ask for diagnostic setup on Upper Arch, with a special instruction note that you will use Invisalign Palatal Expanders.
 - Receive and adjust the ClinCheck to move the mandibular teeth as you desire. You may use
 the ClinCheck to determine the exact expansion you would like to prescribe for Invisalign
 Palatal Expanders (which must be submitted as a separate prescription).
- 2. Order Invisalign Palatal Expanders according to "Invisalign Palatal Expander only workflow" section.

For more detail on how to determine expansion using an Invisalign First ClinCheck, see the 'How do I know how much to expand?' section.

Delivering Invisalign Palatal Expanders



Preparing for delivery and attachment bonding

Prepare for delivery at least 5 days prior to appointment by ensuring the Invisalign Palatal Expanders have shipped or are in your office.

Use Tetric EvoCeram, or another highly-filled composite (see recommended attachment material list).

Pre-fill attachments the day of delivery, before the patient arrives. Two attachment templates are provided.

Prepare any additional materials you typically use for bonding attachments.

Be sure you have written patient instructions available for your patient.

Attachment material recommendation list

The following combinations of bonding agents and composites are recommended for use with the Invisalign® Palatal Expander System based on shear bond testing performed by Align Technology.

Bonding agent	Composite
GC America G-BOND Agent*	handar Tatria Fra Carara*
3M Scotchbond Universal	Ivoclar Tetric EvoCeram*
VOCO Futurabond	VOCO GrandioSO
Kulzer iBond Total Etch	Kulzer Venus Diamond

Note:

- Bonding agents and composites should be used in the recommended combinations (i.e., we don't recommend using a bonding agent from one material type with a composite from another material type).
- These products are not provided with the Invisalign Palatal Expander System; they must be purchased separately.
- Depending on your location, products marked with an asterisk (*) may be sold out on the Invisalign Doctor Site Webstore.

Delivering Invisalign Palatal Expanders



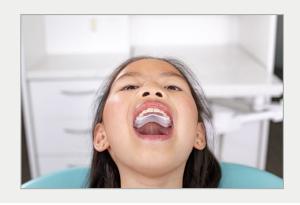
Delivery and attachment bonding

- 1. Insert the Invisalign® Palatal Expander before bonding attachments to test fit.
- 2. For attachment placement, isolate using a use NOLA retractor, or use the isolation technique you typically use when bonding attachments.
- 3. Provide a seater or chewie to the patient to help them seat the expander.
- 4. Have the patient practice insertion and removal chairside.

 Note: there is often a visual and/or audible "click" on both sides.
- 5. If the patient has difficulty seating the expander, try having them seat the expander on one side first and then rotate the other side into place (ideally, start with side where crowns are more tipped toward the cheek).
- 6. If retention of the expander is excessively difficult to remove, consider beveling the attachments with a handpiece.

Invisalign Palatal Expander System patient brochure

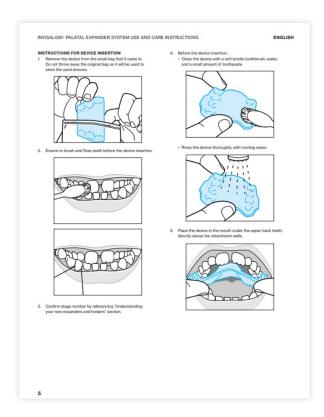
Pro Tip: Instruct the patient to keep all expanders (do not throw them away). Ask the patient to bring all expanders to each visit.





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- What to expect with Invisalign
 Palatal Expanders new patient
 and parent guide
- Patient Instructions for Use

Watch: Invisalign Palatal Expander patient instruction video





Wear protocol considerations



Because the Invisalign Palatal Expander is capable of both dental and skeletal expansion, you may choose to adjust wear protocols, at your discretion.

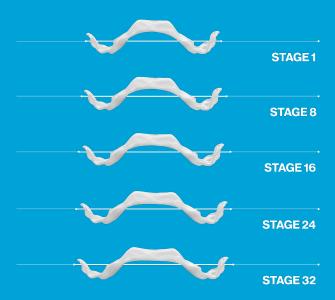
- 1. Conduct a mid-treatment* check to ensure expansion is progressing as expected.
- 2. Instruct patients to notify doctor if any issues are observed (e.g. lack of fit or attachment de-bonding) and save expanders. Adjust expander change frequency or schedule a follow-up appointment to re-bond attachments if needed.
- 3. Instruct patients to wear the device to eat to maintain maximum effectiveness. However, if the patient is unable to tolerate the device during eating, instruct the patient to change out every 2-3 days for the duration of the expansion period.

Pro Tip: : Consider a checkup at stage 10* to assess efficacy of current wear protocol.

At 10 stages, 2.5mm of expansion should be achieved. That is just more than 1mm per side. At that point, if both dental and skeletal tracking are not matched, it is likely to be apparent clinically. A check at this point allows you to alter the wear protocol for your patient to account for individual variation in patient response early on.

You may also choose to check the patient at 7 or 14 days, for example, if that is a better fit for your clinical schedule. The stage(s) at which you check are at your discretion.

Treatment monitoring



- 1. Prepare a list of standardized questions for patients to assess compliance, comfort, and effectiveness.
- 2. If new wear protocol is needed, communicate the new wear schedule and the why
 - a. For example for an older patient or one for whom a large magnitude of expansion is needed, consider moving to changes every other day.
 - b. For a younger patient who cannot tolerate eating with the expander in, 2-3 day changes may better ensure the desired clinical outcome.

Note: In the event a **new** scan is obtained for additional or replacement expanders, attachments may require different placement and must be re-bonded. Allot time in your schedule accordingly. This is the same for ordering holders, however, if expansion is progressing smoothly, you may order the holders without submitting a new scan.

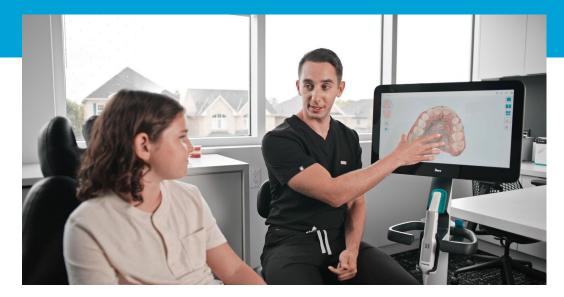
Example check-up visit patient questions

- Fit
 - On a scale of 1-10, how tight does the expander fit?
- Wear schedule
 - · How long are you wearing expanders each day?
 - · Are you taking your expanders out to eat?
 - How frequently are you changing your expanders out?

Comfort

- Are you experiencing any rubbing or irritation against the cheek?
- Insertion/removal
 - Are you using chewies to help seat your expanders?

Stabilization (holding and retention)



on Palatal expansion only, with no alignment planned immediately following expansion

- a. Determine which stage to order holder early on (for example, if you are comfortable with tracking at stage 10, order holders from the final planned stage after the check at stage 10)
- b. Prescribe 2-4week wear for each holder. Stabilize for the number months based on your preferred protocol, just as you would with a traditional expansion appliance.
- c. Full time wear is preferred, but you may move to nighttime and some daytime (14+ hours per day total) wear after an initial period of full-time stabilization.

particle For Palatal expansion with planned alignment to follow in the same phase of care

- a. Determine which stage to order holder early on (for example, if you are comfortable with tracking at stage 10, order holders from the final planned stage after the check at stage 10)
- b. Prescribe 2-4 week wear for each holder. Stabilize for the number months based on your preferred protocol, just as you would with a traditional expansion appliance. OR
- c. Depending on your clinical preference, you may begin alignment after a shorter period of stabilization with holders and use Invisalign Clear Aligners to maintain expansion while simultaneously aligning the maxillary teeth.



Did you know? Invisalign Palatal Holders may be ordered as soon as the expanders are shipped, though you may wish to verify progress before doing so.

Note: If you take a new scan to order holders, the attachment positions change. These attachments need to be re-bonded at the appointment delivery appointment.

Looking for more tips and tricks?





Invisalign Palatal Expander System scanning cheat sheet

Use this cheat sheet in a place that makes the most sense for your practice (i.e. consult room, operatory, or next to your iTero™ scanner)

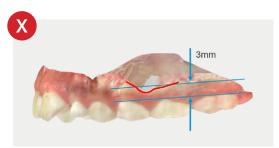
- 1. Perform prophylaxis of the patient's teeth to remove plaque around gumline to expose as much of the surface area of the tooth crown as possible.
- 2. On the scanner, select **Invisalign | Vivera** procedure and **Invisalign Palatal Expander** procedure type.
- 3. When scanning for palatal expansion treatment, your scans must capture the palate, gingiva, and crown surface.

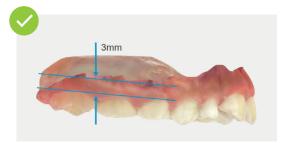
Crown coverage

1. Ensure there are 3 stable teeth per quadrant on the upper arch with at least 4mm of crown height for each tooth.

Gingival coverage

The gingival scan should capture **3mm or more** beyond the gingival or cementoenamel junction (CEJ) line.





- 1. Rejected gingival scan example
- 2. Accepted gingival scan example

Palatal coverage

The palatal scan should be captured up to a line connecting the distal surfaces of the upper first permanent molars or terminal molars with **no visible voids**.







2. Accepted palatal scan example

Pro Tips:

- 1. Scan 2mm past the distal surfaces of the upper first permanent molars or terminal molars, ensuring a smooth continuous line of palatal tissue is captured in the scan with no visible voids.
- 2. If any part of the tissue was removed while reviewing the model, disable the A.I. Cleanup feature (if your iTero is not an iTero Lumina™ intraoral scanner) to bring back

