

Vivos Appliance User Guide

Instructions for the Dentist



Device Description

The Vivos appliances consist of the Vivos DNA appliance, the Vivos mRNA appliance, and the Vivos mmRNA appliance.

The Vivos DNA appliance consists of an upper and/or lower customized tray. Each device is customized with one or more adjustment mechanisms that enable the device to cause the desired tooth repositioning or jaw expansion for each patient.

The Vivos mRNA appliance and Vivos mmRNA appliances consist of two customized trays that fit over the upper and lower teeth. The appliances feature an adjustment mechanism (expansion screw) to allow them to be further customized to each patient.

Intended Use

The Vivos DNA appliance is intended to reposition teeth, straighten teeth, and/or expand the jaw for orthodontic treatment.

The Vivos mRNA appliance and Vivos mmRNA appliance are both personalized-per-patient devices that are intended to be used to reduce nighttime snoring and mild to moderate sleep apnea in adults.

Directions for Use

Caution: Federal law restricts this device to sale by or on the order of a dentist.

Vivos appliances generally consist of at least one upper and/or lower trays that are customized to fit the patient's dentition and adjacent tissues and are generally worn by the patient while sleeping and during the day, as indicated by the Vivos dental provider.

The Vivos DNA appliance is worn to help reposition the teeth and expand the jaw. The Vivos DNA appliance may be adjusted in the anterior-posterior (AP), transverse (TV), and vertical dimension of occlusion (VDO), as indicated clinically.

The Vivos mRNA and Vivos mmRNA appliances help maintain a patient's oropharyngeal airway by limiting the ability of the mandible to move posteriorly when the patient is sleeping or by repositioning the mandible as indicated. The Vivos mRNA and Vivos mmRNA appliances may be adjusted in the anterior-posterior (AP), transverse (TV), and vertical dimension of occlusion (VDO), as indicated clinically, to reduce snoring and/or mild to moderate obstructive sleep apnea in patients who respond to this type of device.

Vivos appliances are inserted by inserting the upper plate until it is securely and comfortably fitted, followed by the lower plate. Sometimes a "rocking" motion is helpful to remove the plates in the morning, where the lower plate should be removed first, followed by the upper plate.

For Vivos mRNA appliances, ensure the vertical wire fins will engage with the upper plate, preventing the lower jaw from moving backward during sleep.

Vivos appliances should be cleaned with soap and water and rinsed thoroughly daily. Toothpaste should not be used to clean the device. A denture or retainer cleaning solution can be used no more than twice a week to soak and clean the device if desired.

The patient should be instructed to look for damage to the device, including cracks in the acrylic and loose wires, before use.



Fitting Instructions for Dentist

1. The Vivos dental provider should properly sanitize the Vivos appliance prior to handling and patient insertion after receiving it from the manufacturer and at each follow-up visit.
2. Check the fit of the Vivos appliance's upper tray and adjust the acrylic and/or wire clasps and/or screws as needed for a comfortable yet retentive fit. Check the palatal fitting surface and posterior border; use pressure indicator paste to ensure approximately 0.25 mm between the oral mucosa and the appliance. Check the labial bow; it needs to be approximately 0.25 mm off the labial surfaces of the teeth. Check the 3D axial springs; they need to be in intimate contact with the palatal surfaces of the teeth.
3. Once the upper tray is fitted, remove it and fit the lower tray in the same fashion. Once both trays are fit individually for comfort and retention, insert the upper tray, followed by the lower tray, and check the fit of the complete appliance for comfort and retention.
4. With the upper and lower trays in place, check that the mandibular position is consistent with the initial bite registration (i.e., check that the dental midline is appropriate and not being shifted significantly).
5. Check the posterior contact on the occlusal pads with articulating paper to confirm that the occlusion is even on each side. The height of the occlusal pads may be reduced with an acrylic bur if less height is needed.
6. For Vivos mRNA and Vivos mmRNA appliances, if the patient feels significant pressure in their jaw from excessive protrusion, adjust the AP adjustment mechanisms to the appropriate initial mandibular position. Excessive protrusion of the mandible is not recommended. For Vivos mRNA appliances, check that the vertical wire fins are engaged in the upper acrylic slots bilaterally.
7. After final polishing of the Vivos appliance, seat the appliance and allow the patient to wear it for several minutes. Adjust any areas of the appliance that the patient finds uncomfortable.
8. Review the patient instructions regarding the use and care of their Vivos appliance and what to expect as they begin treatment. Explain the potential side effects and what the patient should do if they experience any pain, discomfort, or changes to their normal bite. A thorough TMJ evaluation before fitting the Vivos appliance is indicated, as is the evaluation of any sensitivity of the TMJ in the follow-up visits.

Contraindications

Do NOT use your Vivos appliance if

- you have central sleep apnea;
- you have loose teeth, bone loss/periodontal disease, or poor oral hygiene ;
- you have an active TMJ disorder;
- there is damage to or visible breakdown of the appliance;
- you have severe respiratory disorders; or
- you have insufficient teeth for retention of the device.

Patients who are 18 years of age or younger should NOT use either the Vivos mRNA appliance or Vivos mmRNA appliance.

Warnings

Use of the Vivos Appliance may cause the following:

- **Tooth movement or changes in dental occlusion.**
- **Jaw, tooth, or dental soreness.** You may experience soreness or discomfort in your jaw or teeth, particularly at the start of use of the Vivos appliance or after an adjustment of the device.
- **Obstruction of oral breathing.** When the device is properly fitted and inserted, you should not experience obstruction of oral breathing with the appliance in your mouth.
- **Excessive salivation.** This is normal in the first few weeks of wear.

Precautions

Dentists should consider the medical history of patients, including the history of asthma, breathing or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.