

The logo features the word "VIVOS" in a white, sans-serif font. To the right of the text is a stylized graphic consisting of three overlapping teardrop shapes: a light green one at the top, a yellow one at the bottom, and a light blue one on the right side. A registered trademark symbol (®) is located at the bottom right of the word.

VIVOS®

Vivos Appliance User Guide



Instructions for Use



Overview

Vivos appliances are customized intraoral appliances fabricated from biocompatible materials that may only be fitted by a Vivos dental provider. Your Vivos dental provider has been educated and trained with the tools to teach you how to use and care for your Vivos appliance. The following information and instructions are supplemental to the information and instructions from your Vivos dental provider. Should you have any questions about the use or care of your Vivos appliance, please contact your Vivos dental provider. The Vivos appliances consist of the Vivos DNA appliance, the Vivos mRNA appliance, and the Vivos mmRNA appliance.

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.

Device Description

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.

Use of the Vivos Appliance

Caution: Federal law restricts this device from sale to the general public. This device is only accessible by the order of a licensed dentist.

In general, Vivos appliances can be worn in the mouth for several hours during the day and while sleeping at night. A Vivos dental provider will thoroughly cover the proper usage of your Vivos appliance with you.

Inserting the Appliance

Always clean your teeth properly before placing your Vivos appliance to minimize the possibility of getting food and debris getting stuck in it. Some patients prefer to rinse their Vivos appliance in water before placing it in the mouth. This is your preference.

At the beginning of your treatment, it is helpful to use a dental mirror to insert your Vivos appliance for proper fitting and placement.

Place your upper Vivos appliance in first. Use the dental mirror to position your Vivos appliance with the front wire bow on the outside of your upper teeth. When you feel the appliance is centered over your upper teeth, gently and firmly push the acrylic pads with your thumbs to snap the appliance in place. It is imperative not to force the appliance into place. If you feel it is not an easy and smooth fit, you should contact your Vivos dental provider promptly.

Do not push on any of the wire components to place the appliance.

Do NOT bite the appliance in place, as this could cause damage to your appliance and/or your teeth.

When your upper Vivos appliance is securely in place, use the dental mirror to help position your lower appliance with the wire bow on the outside of your lower teeth. Use your fingers to gently and firmly push down on the acrylic pads to snap your Vivos appliance in place—again, not forcing the appliance into place.

A note regarding the Vivos mRNA and Vivos mmRNA appliances:

The use of the upper and lower trays of the Vivos mRNA and Vivos mmRNA appliances will reposition the lower jaw forward. The forward position has been professionally determined by your Vivos dental provider doctor as a starting point for your treatment. This position may or may not change during treatment, according to your needs and the response of your body. You should have some limited freedom to move side to side and forward, but not backward.

Do not attempt to alter or adjust this position yourself unless specifically instructed by your Vivos dental provider, as any interference by you to the device may disrupt the treatment designed specifically for you.

Removing the Appliance

In the morning, the protocol is reverse from inserting your appliances, as you will now remove by starting with the lower Vivos appliance first. Lift the lower appliance from the back sides of the device in the lower molar area. Sometimes, a “rocking” motion is helpful to get the Vivos appliance to disengage, pulling slightly to one side and then the other. Do not use the front wire bow to remove the appliance.

Once the lower appliance is out, use your fingers on the back sides of the upper appliance to pull down from the teeth. A “rocking” motion can be helpful here as well. Do not use the front wire bow to remove the appliance.

It is important to remember to be gentle when removing your Vivos appliances to ensure that your device and your teeth are handled with proper care.



Care & Cleaning Instructions



Regularly Inspect Your Vivos Appliance

Regularly inspect your Vivos appliance(s) for signs of damage, cracks, loose wires, etc. If your Vivos appliance is damaged, immediately take it to your Vivos dental provider for repair or replacement. Failure to do so may result in injury, including swallowing or aspiration (breathing in) of pieces of the device while sleeping. Delay in getting adjustments could allow changes in your dentition so that the appliance cannot be easily adjusted.

Cleaning and Storage

Upon removing your Vivos appliance after use, always clean it thoroughly following the cleaning instructions below.

- Clean your Vivos appliance after each use with mild soap, cool to lukewarm water, and a soft toothbrush, and rinse thoroughly immediately after having removed the appliance from your mouth.

If the above method has not been followed, a deeper cleaning may be needed. In such instances, a sodium bicarbonate-based retainer tablet cleaning solution may be used from time to time to soak your Vivos appliance in.

- DO NOT soak the device longer than 15 minutes or more once a week. To do so puts your appliances at risk of the erosion of the metal parts and may cause the acrylic portions to become brittle and easier to break.

- Never soak your appliances in hot water, as hot water may damage your device.
- After soaking your appliance for approximately 15 minutes, brush it thoroughly with a soft toothbrush and rinse it under cool to lukewarm water.

When not in use, your Vivos appliance should be thoroughly dried and stored in the case your appliance came with.

Cautionary Items

- Do not store your Vivos appliance in direct sunlight.
- Do not leave your Vivos appliance in extreme temperatures in excess of 45°C (113°F).
- Do not soak the Vivos appliance in mouthwash, as studies have shown it can weaken the integrity of the appliance.
- Do not put the Vivos appliance in hot or boiling water, a dishwasher, or a microwave.

- Do not use toothpaste, as it contains abrasives and may damage your Vivos appliance.
- Do not wrap your Vivos appliance in a napkin or tissue during meals, as it can easily be discarded.
- Do not carry your Vivos appliance loosely in a pocket or purse, as it can become damaged.
- Store your Vivos appliance in the case that came with it and out of reach of pets who can chew on them.
- Report any damage or wear problems to your Vivos dental provider immediately.

Important

With regular use of your Vivos appliance, it is not uncommon for your appliance to discolor. Such discoloration will not adversely affect the performance or longevity of the device. Oftentimes, patients who drink coffee, tea, or cola with the device in place may see more discoloration in their appliance than those who do not.

Track Your Progress

At each follow-up appointment with your Vivos dental provider, you will need to bring your Vivos appliance, the retainer case, and a log or diary of your wear and comfort.

At each visit, your Vivos dental provider should provide you a card or sheet for logging what days/nights you wear your Vivos appliance, how many hours you wore your Vivos appliance during the day and night, and any notes about any issues you might have had in between visits. It is very important to make your Vivos dental provider aware of any complaints or matters that may have arisen with your appliance since your last dental visit.

Even after the completion of active treatment, your Vivos dental provider may continue to reevaluate you and the need for further treatment regularly.

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.

Possible Side Effects

Use of the Vivos Appliance may cause the following:

- **Tooth movement or changes in dental occlusion.**
- **Jaw, tooth, or dental soreness.** You may experience some 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.

If any of the above are experienced or persist, or if you have any questions regarding the proper use or care of your Vivos Appliance, contact your Vivos dental provider immediately.



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