



# Instructions to Dentists for the Vivos Guide vStarter, Vivos Grow and Vivos Way appliances

## Device Description

The Vivos Guides are FDA registered Class I removable dental appliance tooth positioner that straighten and reposition teeth, and/or expand the jaws for orthodontic treatment. Additionally, Vivos Guides may improve bad oral habits such as tongue thrusting, thumb and finger sucking, speech problems, mouthbreathing, swallowing and dental conditions such as upper arch constriction, crossbites, and bruxism.

## Intended Use

The Vivos vStarter appliances may be used in patients as early as 4 years of age and older. The appliance is designed to be worn passively for 8-10 hours while sleeping to reposition and straighten the teeth. The dentist may also prescribe it for use for 1-2 hours during the day. No adjustments are generally necessary.

There are minor differences in the appliance selected for a patient based on their current level of dentition. For patients who do not have permanent molars, the vStarter for Kids is selected to allow the 1st molars to erupt. For children who have at least their first permanent molars in, the vStarter is selected to ensure proper fit and that there is not an over-eruption of the 1st permanent molars.

The Vivos Grow (VG) is designed for patients with mixed dentition who may have one or more of the following dental conditions such as crowding, spacing, overbite, and overjet. The Vivos Grow may also help to guide erupting teeth and jaws orthodontically into an ideal position. Additionally, it may also help to guide erupting teeth into an ideal position, correct molar relations, expand the jaws, improve teeth rotations, crossbites, bruxism and upper arch constriction.

The Vivos Way (VW) is designed for patients with the adult dentition who may have one or more of the following dental conditions such as crowding, spacing, overbite, and overjet. The Vivos Way may also correct molar relations, teeth rotations, expand the jaws and address other dental conditions such as crossbites, bruxism and arch constriction.

## Directions for Use

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

The following are general directions for use for the treating dentist. Specific protocols and directions may be varied, and a patient's complete health history should be considered by a qualified treating dentist prior to treatment with a Vivos Guide.

Patients are encouraged to wear all Vivos Guides while sleeping at night during active treatment.

Patients are instructed NOT to bite on any Vivos Guide in any other way than directed, like gnawing on the ends, tabs, outer or inner flanges, etc.

The patient should visit the treating dentist every 4-6 weeks after the Vivos Guide has been delivered for the first 6 months of use. After that, the patient may return every 3-6 months to the trained dentist to ensure patient compliance and the integrity of the device. Vivos Guides may need replacement after approximately 12 months of use.

At the discretion of the treating dentist, the use of the Vivos Grow and the Vivos Way Guides may require active wear during the day. Active wear treatment consists of 1-4 hours per day of day time wear, where the patient bites or clenches down into the Vivos Grow or Vivos Way for one minute or more, then relaxes for 30 seconds. Active wear may be completed in 20-minute or more increments throughout the day, or as directed by the treating dentist.

The device should be cleaned with toothpaste and a toothbrush daily. Patients and their parents should be instructed to look for unusual damage to the device, beyond normal wear and tear, including cracks or other damage, before use. They should report any damage to their treating dentist immediately for replacement.

## Fitting Instructions for Dentist

1. Screen, diagnose, establish treatment objectives and a treatment plan to determine whether the patient is appropriate for treatment.
2. If it is determined that a vStarter is needed, select the appropriate vStarter based on whether the patient's 1st permanent molars are present or not. The Vivos Starter for Kids are for those patients whose 1st molars have not yet erupted. The Vivos Starter are for those patients whose 1st molars have erupted.
3. If a Vivos Grow or Vivos Way Guide appliance is needed, a measurement of the patient will need to be taken in order to determine with size of Guide is to be used.
  - a. The appropriately sized Vivos Grow or Vivos Way Guide is selected by measuring the mesio-distal widths of the upper 4 incisors and combining their totals. This number is called the Swartz Index and can then be compared with a Vivos Sizing Chart and the correct size can be selected.
2. When delivering the patients Vivos Guide, rinse in lukewarm water before inserting in the mouth to prevent condensation which can temporarily block the appliance's transparency.
3. Place the proper sized Vivos Guide in the mouth, lining up the midline mark with the center of the mouth
4. Have the patient occlude into the appliance troughs
5. In fitting the Vivos Guides, check for gingival impingement. If impingement is noticed, it may be necessary to trim the appliance.
6. After the Vivos Guide has been delivered, it is important to establish routine visits to ensure that treatment is proceeding successfully. Regular visits once every four to six weeks during the first 6 months of treatment are important to ensure that active treatment is progressing as planned. Soft tissue and dental changes should be seen within the first 1-3 months.
  - a. Updated photos, models and questionnaires should be taken at every appointment.
  - a. An updated CBCT scan and HST should be taken approximately 12 months into treatment (for patients 5 years of age and older), and/or once the patient is dismissed from treatment.

## Contraindications

The following patient conditions or symptoms may be contraindications for treatment with the Vivos Guides series of appliances.

- Have central or severe sleep apnea
- Have severe respiratory disorders
- Have severe TMJ where there is limited opening (2 fingers or less)
- Have loose teeth, significant alveolar bone loss/ advanced periodontal disease
- Have insufficient permanent or deciduous teeth for retention
- Have root damage, root resorption with overbite  $\geq$  3mm
- Have suspected problems of cyst, bone issues, radiolucent areas
- Have dentures, braces or are using other dental appliances
- Excessively narrow palate with bilateral crossbite
- A Skeletal Class III malocclusion
- Have crowns, implants, or caps, unless otherwise approved by their dentist

Other problems might exist in which the dentist must decide before proceeding

## Warnings

Use of the device may cause:

- Tooth movement or changes in the dental occlusion
- Gum or mouth tissue soreness and/or soreness of the teeth
- Pain or soreness of the temporomandibular joint(s)
- Obstruction of oral breathing
- Excessive salivation

## Precautions

Dentists should consider the medical and dental history of patients, including 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.