Precautions

It is essential that the patient have a diagnosis by testing with a home sleep testing device or an overnight-attended PSG (PolySomnogram-diagnostic sleep test). Additionally, to verify the efficacy of the treatment testing needs to be performed by a sleep physician.

Appliance performance may be adversely affected by: weight gain, obesity, alcohol consumption, sedative use, smoking, very high altitudes, aging, hormonal changes, i.e. menopause, a cold, or sickness that compromises nasal breathing.

Be sure to keep the expansion screws clean. Examine them often for signs of wear and tear. If you suspect that damage has occurred, advise patient not to wear appliance and contact True Function Dental Laboratory for possible repair.

For storage and maintenance, advice patient to completely air-dry appliance after each cleaning with a clean tissue or towel, and place it back in the storage container.

Use of the appliance may cause:

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint, or facial muscles
- Obstruction of oral breathing
- Excessive salivation
- Loosening and/or dislodging of dental fillings or crowns

A small percentage of patients actually increase their number of apneic and hypopneic events during use of oral appliance. Should your patient experience any of these adverse events, instruct them to discontinue use of the appliance and contact your office immediately.

Contraindications

The appliance is contraindicated for patients who:

- Have central sleep apnea
- Have severe respiratory disorders
- Have myofacial dysfunction
- Have loose teeth or advanced periodontal disease
- Have few or no teeth to retain the appliance
- Have inadequate range of motion of your lower jaw
- Are undergoing orthodontic treatment
- Are undergoing dental work that requires temporary crowns

Clinician Instructions

TrueFunction® Adjustable Herbst Appliance

The use of TrueFunction® Adjustable Herbst Appliance is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

The TrueFunction® Adjustable Herbst Appliance is a prescription only appliance, that is customized by True Function Laboratory to dentist specific instructions.
Pre-Appliance Fabrication Instructions

Preparing the Prescription
Perform a complete oral health assessment as well as a medical history assessment including:
- Full medical and dental health history
- Dental radiographs
- Clinical oral evaluation
- General patient interview

Dentist needs a referral from a physician for fabrication of an oral appliance.

Taking the Impression
Impressions should be taken of the upper and lower arch including the palate using alginate or VPS impression material. It's highly recommended that impressions be poured in stone at the dental office to evaluate for any defects. Once completely dried and trimmed, they are ready to ship to True Function Laboratory.

Pre-Appliance Fabrication Instructions

Record The Bite
A bite record is necessary for the dental laboratory to construct an appliance that positions the jaws in the proper relationship to one another. Follow these simple steps to accurately record the bite:
- Use a hard wax or elastomeric material to record the bite relationship in the patient’s mouth.
- Use a Gauge to measure the range of motion of the mandible along its anterior-posterior travel.
- Set the gauge at a fixed position, approximately 70% protruded (widely accepted starting point for therapy) from the most retruded position. If the 70% protrusion can’t be attained comfortably, take the bite record at the most comfortable protrusion position.
- After setting the gauge, insert it in the mouth and have the patient practice closing into the notches on the bite forks. Then remove the gauge from the patient mouth and place softened wax or elastomeric material on both sides of the bite fork component. Have the patient bite down into that material until it sets or hardens.

Note: Articulate the models (with the bite record). Make sure that the models fit into the bite record without rocking. Ensure the skeletal midline is aligned and the models are properly settled. The bite record should then be packaged securely and shipped along the models.

Observations/Adjustment Visits
Schedule follow-up observation visits to ensure that the appliance is comfortable and effective and that no dental problems have developed. The following is a suggested follow-up schedule:

Week 1 - Make any necessary adjustments for the fit and positioning. Adjustments are usually made in increments of 0.5mm
Month 1 to 3 - Evaluate teeth and appliance and make any necessary adjustments in jaw position
Month 6 - Check progress with the appliance and address any patient concerns
Annually - Inspect teeth and appliance to minimize possible side effects and make any necessary appliance repairs or adjustments

The maintenance care regimen is very important. Insisting on regular follow-up visits from your patient ensures a proper fit for the best possible treatment with the appliance. Advise patient to completely air-dry appliance after each cleaning with a clean tissue or towel before returning it to the storage container.

Sterilization

TrueFunction® Adjustable Herbst Appliances are reusable medical devices (single user) and are supplied non-sterile. However, it's recommended that the patient follow these basic and normal hygiene instructions for proper cleaning and care of the device.

After each use, rinse the appliance in cold or lukewarm water
Gently brush all surfaces with a mild soap and soft toothbrush
DO NOT USE TOOTHPASTE. It will abrade the appliance
Gently rinse the appliance with cool clean water
Completely air-dry the appliance before storing

Patient Fitting
Prior to delivering the appliance, it should be properly washed and disinfected with solution like Cavicide®, by following the manufacturer recommend use. As suggested by the manufacturer, the appliance should be sprayed on all surfaces, allowing it to remain wet for 3 minutes at room temperature. Then, rinse throughly with clean water.

Appliance Advancement Mechanism

The dentist can advance the device using the orthodontic expansion key enclosed with the device.

Device Advancement Mechanism

- Each arm has a turnbuckle towards the front where it attaches to the lower tray. There are four holes along the outside of the turnbuckle and each hole is equal distance from the next.
- Next to the expansion hole are marks with the (+) and (-) symbols. The (+) means protrude or advancement; the (-) means to retrude or retraction.
- A full 360 degree turn on a single hole equals 1/4mm of advancement.
- A half turn (from the bottom to the top or top to bottom in direction of the (+) symbol) equals 1/8mm. A quarter turn (every time next hole appears) equals 1/16mm.
- Maximum advancement is 5mm.

Advancing the device

To protrude / advance the mandible:
- To bring the arm forward, place the expansion key into hole and rotate in the direction of the (+) symbol.
- Every time a new hole appears in the position of the hole being turned, the advancement is 1/16mm.
- Expand both arms the same amount to make symmetrical adjustments (protrusion).