DOCTOR'S INSTRUCTIONS:
THE FULL BREATH SOLUTION APPLIANCE

OVERVIEW

The Full Breath Solution (FBS) is a single-arch oral appliance, designed to gently keep the mouth open, the air passage free. While other mouthpieces are focused on advancing the mandible to pull the tongue forward, the Full-Breath Solution focuses on the tongue itself. Fully patented, it inhibits the movement of the tongue, thus eliminating potential jaw pain or TMJ problems.

• No mandibular advancement
• No jaw or facial pain
• No malocclusion
• No creation of spacing between teeth

Worn only at night, each thermoplastic-formulated FBS appliance is custom-made and form-fitted to each patient’s mouth. The treatment process is simple: an accredited laboratory sleep test (or Home Sleep Test from SML™ (1-800-423-3270), www.SMLsleep.com.

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 mouth and place softened wax or elastomeric material on both sides of the bite fork component. Note: For best results, it is essential that the wax is soft when placed in patient’s mouth. Have the patient bite down into that material until it sets or hardens.

IMPORTANT: Make sure that the models fit into the bite record without rocking. Articulate the models (with the bite) to ensure that the skeletal midline is aligned and the models properly settled. The bite record should then be wrapped in bubble wrap and included with models sent to the lab.

Shipping the Case:
Models and bite records should be wrapped with bubble wrap and shipped to our certified laboratory in a box -- along with a prescription for the Full Breath Solution Appliance.

Disinfection (prior to dispensing appliance):
Prior to patient contact, the new appliance should be properly washed and disinfected. After disinfection, a thorough rinse with high quality potable water is then required. All warnings and precautions should be strictly observed.

Delivery (to the patient):
The delivery visit should confirm the fit and comfort of the appliance -- as well as the patients’ ability to insert and remove it properly and without difficulty. It may be necessary to adjust the appliance in order to achieve a comfortable level of retention.

The upper front teeth should feel comfortable with the appliance in place. An acrylic lab bur can be used to relieve any pressure spots on the inside of the appliance. The appliance is designed to allow the mandible freedom of movement side-to-side, vertically, and protrusively.

IMPORTANT NOTE: Patient Use Instructions (including risks and benefits, care, maintenance, and warnings) must be dispensed and reviewed with the patient at this visit.
Study and pharyngometer), followed by a fitting, then three to eight follow-up visits for adjustment and fine tuning. Replacement is projected for every three to seven years, depending upon patient wear and care... and the FBS treatment is covered by most medical plans.

CONTRAINDICATIONS
Placement may initiate immediate gag response
Wear may hinder ability to swallow, and consequently interfere with sleep
Appliance should not be used with periodontally compromised patient

RISKS
Use of the device may cause unwanted tooth movement (rare)

Important Note: Should your patients experience any of these adverse events, instruct them to discontinue use of the device and call your office.

SEATING INSTRUCTIONS
THE SEATING APPOINTMENT IS KEY TO ESTABLISHING COMFORTABLE FIT AND ENSURING CONTINUED PATIENT WEAR.

1. Seat the appliance as it comes from the lab.
2. If the patient is comfortable with the seating of the “tail” of the appliance, then NO CHANGES are necessary at this appointment. Instruct the patient to return in one week – a typically sufficient amount of time for patient comfort conditioning.

NOTE: If you have a Pharyngometer, it may prove helpful to take readings (with and without appliance in place). An immediate change can serve as an indication of treatment direction.

SEATING ADJUSTMENT PROTOCOL
Should a patient experience a gag reflex and/or swallowing inhibition once the Full Breath Solution appliance is seated, please take note of the following adjustment suggestions:

1. In the event of gag response or difficulties in swallowing – immediately or upon the patient’s return to your office a week later for first adjustment - start by removing the “tail” on the appliance.
2. If the gagging or swallowing problem persists, the translingual bar needs to be “arched up” to reduce contact on the underside with the tongue. This is achieved by first adding acrylic to the superior surface of the bar. Acrylic is then removed – at the lathe or via hand piece – from the inferior of the bar. As a result, the arch is made ¼ inch higher. This will resolve the problem with most patients.
3. If the initial raising of the arch of the bar by ¼” does not alleviate the swallowing or gagging problem, repeat the same above procedure by an additional ¼”.

Should sensitivity persist, call the Full Breath Office at 888-285-8038, OR EMAIL Dr. Keropian at bk@cpapalternative.com.

Dr. Keropian will be happy to work with you in handling the very small percentage of patients who experience unusual sensitivity. General protocol on such rare occasions calls for the removal of the translingual bar...

Step One: Cut off the translingual bar and create a bruxism appliance. NOTE: Save the cut-off arch in a small x-ray envelope.

Step Two: Have the patient wear this design for three weeks. Then reattach previously-removed translingual bar. Typically, the patient will be comfortable with the appliance in place.

Step Three: Once the patient voices comfort with the new fit, reverse the process – extending the tail down in 2-4 increments until satisfactory contact is achieved. NOTE: Again, should you require assistance or walk-thru guidance during this potentially challenging adjustment process, please feel free to call upon the staff of experts at Full Breath Solutions.

OFFICE PROTOCOL
Oral Health and Medical Health History Assessment:
The dentist must perform a complete oral health assessment as well as a medical health history assessment including;

Full medical and dental health history
Dental radiographs
Clinical oral evaluation
General patient interview

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

Impressions:
Dental impressions of the upper arch of teeth and palate and the lower teeth should be taken – using a high quality alginate such as Kromopan or PVS impression material. We recommend that impressions be poured in your office, evaluated for defects, trimmed and dried before shipping to the laboratory.

Bite Records:
In order for the laboratory to construct an appliance that positions the jaws in the proper relationship to one another, it is necessary to record this relationship (in the patient’s mouth) with a hard wax or elastomeric material. The following steps are recommended:

Using an Andra or George Gauge or a Perfect Bite, get a centric relation bite (at approximately a 2mm vertical opening). All gauges are available...