



FDA 510K
and
Medicare
E0486
Cleared



The **OASYS Hinge Appliance** is FDA and Medicare cleared for Sleep Apnea. The side hinges are set to hold the lower jaw forward during sleep, but allows the patient to open and close his/her mouth and have some side to side movement (Usual open 2mm to allow Retraction). This will help to open the airway in back of the throat, while pulling the tongue forward.



Inserting the OASYS Hinge Appliance—The Device will be inserted as one piece, placing the upper splint on the upper teeth first and then sliding the lower teeth up into the lower splint. If this device is marked __ “Made in ThermoFlex Hard Resin”, it is recommended that you dip the device initially in microwave water for 3 seconds for ease of insertion. This will provide a slight flex in the material so the splints will seat easier. The patient should be encouraged to run the device under hot tap water for 5-10 seconds initially, but this may not be necessary with continued wear. It may be beneficial for the patient to wear the device while watching TV or reading before going to bed, to get more comfortable having this device in his/her mouth.

Titration the OASYS Hinge Appliance

We set the Oasys Hinges open 1mm or 2mm, so you can decrease protrusion, if needed. The hinges have anterior advancement holes and the Hex Driver is used to advance in 1/2 turns clockwise...2 Full Turns = 1mm). Insert Hex Driver with “Protanium Steel” at 12:00. For 1/4 mm advancement, Turn Clockwise until the Bondus inscription is at 12:00. For 1/2mm Advancement, Turn the Hex Driver Clockwise so “Protanium Steel goes around one full turn and is at 12:00 again. For 1mm advancement, Turn the Hex Driver Clockwise 2 Full Turns until “Protanium Steel” is a 12:00. Turning the screw counterclockwise will decrease the extension of the lower jaw. 5/16"- elastics are included to limit the jaw movement and minimize dislodgement of the splints. The patient can change the elastics as needed, or choose not to wear them. The Hex Driver can also be used for periodic tightening of the Screws on each end of the T-10 Hinges.

Common Side Effects of initial wear are clenching, sore teeth, TMJ sensitivity and increased salivation, but usually resolve in ten days. If more severe pain occurs, the patient should contact you immediately. After wearing the appliance all night, the patient’s lower jaw may be in a more forward position and his/her teeth may come together differently in the morning when it is removed and make take 15-60 minutes to return to a normal position. Massaging the jaws, opening and closing the mouth, doing other exercises, chewing gum or an AM Aligner can help return the patient’s bite jaw to a normal position.

To Clean the Device, brush it carefully with a soft toothbrush and anti-bacterial soap. Let the device dry during the day with the lid of the container left open, to minimize odor. A non-alcoholic denture cleaner can be used for 15 minutes. Do not soak in water, bleach, ammonia or peroxide and keep out of reach of dogs!

Follow-Up Sleep Study—if the patient has Moderate to Severe Sleep Apnea, he/she will need to schedule a follow-up sleep study when you feel that the patient is are subjectively feeling and sleeping better with the device. This will verify the effectiveness of the Oral Appliance Therapy and identify if further adjustments, modifications or combination treatment may be needed.