

The delivery visit should confirm the fit and comfort of the appliance, as well as the patients' ability to insert and remove the appliance properly and without difficulty. It may be necessary to adjust the clasps to achieve a comfortable level of retention.

NOTE: The Patients' Directions for Use MUST be dispensed and reviewed with the patient at this visit.

INSERTION:

- 1. Seat the upper appliance first by gently pressing it up into place with your thumbs.
- 2. Place the lower appliance against the upper appliance. Then bring the patients mandible forward and carefully seat the lower appliance by pressing down with forefingers to finish the seating of the appliance.

The patient 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.

REMOVAL:


- 1. Remove the lower appliance first, using thumbs on both sides to carefully lift it off the arch.
- 2. Remove the upper appliance by carefully pulling down on the sides of the appliance with fingers.
- 3. Rinse and clean the appliance.

AFTER USE:

Some patients may feel that teeth do not occlude properly. Restore the patients bite relationship by using the SML® Good Morning Positioner (included with every sleep case from SML).

ADJUSTMENTS MADE BY DENTISTS OR PATIENT

Turning the hex driver clockwise to advance the mandible in .25mm increments.
Turning hex driver counterclockwise decreases advancement in same increments.



¼ mm advancement – Turn the Hex Driver clockwise 180° i.e. one-half turn
½ mm advancement – Turn the Hex Driver clockwise 360° i.e. one full turn
1 mm advancement – Turn the Hex Driver clockwise 720° i.e. two full turns

PLEASE NOTE:

- 1. All Oasys Herbst Hinges are preset with 2mm pre-activation permitting up to 2mm retrusion, if necessary.
- 2. 3/16" vertical elastics are included if required. These elastics help keep the upper and lower arch together causing a "lip seal". Place the elastic on hook in the upper cuspid area of appliance down around the lower retention screw..
- 3. Use the Hex Driver to periodically assure that the screws attaching the Hinges to the appliance are tight.

FOLLOW-UP/ADJUSTMENT VISITS:

Schedule follow-up visits to ensure that the appliance is comfortable and effective and that no dental problems have developed.

If additional mandibular advancement is necessary, adjustments may be made while patient is wearing the appliance or have the patient remove their appliance. Be sure to advance the appliance bilaterally and record the millimeters of adjustment made.

Week 1: "Comfort Check." Make any necessary adjustments for the fit and positioning. Adjustments are usually made in increments of 0.5mm

Months 1, 2, and 3: Evaluate teeth and appliance. Make any necessary adjustments.



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SPACE MAINTAINERS
LABORATORIES

Item # 63250AS



CAUTION: Federal law requires a written prescription, signed by a licensed medical professional.

CLINICAL INSTRUCTIONS FOR USE:
ADJUSTABLE HERBST APPLIANCE - OASYS HINGE ACRYLIC

The **Adjustable Herbst Appliance-OASYS Hinge-Acrylic Appliance** is fabricated in hard acrylic with ball clasps. The ball clasps can be adjusted to increase retention as needed and is especially effective for patients who lack sufficient natural undercuts. Elastic hooks are included on the upper portion of the appliance so that vertical elastics can be used to maintain a comfortable closed-mouth posture if the patient is a mouth breather.

CONTRAINDICATIONS

This appliance is contraindicated if the patient:

- Has Central Sleep Apnea (CSA)
- Has severe respiratory disorders
- Has loose teeth or advanced periodontal disease
- Is under 18 years of age
- Is edentulous or insufficient number of teeth to retain the appliance
- Has inadequate mandibular range of motion
- Has myofacial dysfunction
- Has arthropathy of the TMJ
- Is undergoing any type of orthodontic treatment
- Is undergoing dental work that requires temporary crowns

WARNINGS

Use of the appliance may cause:

- Tooth movement
- Changes in occlusion
- Gingival irritation or dental soreness
- Pain or soreness of the TMJ or facial muscles
- Increased salivation
- Loosening and/or dislodging of restorations

NOTE: A small percentage of patients actually increase their number of apneic and hypopneic events when using an oral appliance. **Should your patients experience any of these adverse events, instruct them to discontinue use of the appliance and call your office.**

PRECAUTIONS:

- Upon removal of the appliance, many patients may feel that their teeth do not occlude properly.
- Performance may be adversely affected by: weight gain, obesity, alcohol consumption, sedative use, allergies, smoking, very high altitudes, increased age, hormonal changes such as menopause, a cold, or sickness that compromises nasal breathing.

IT IS ESSENTIAL THAT THE PATIENT BE TESTED WITH A HOME SLEEP TESTING APPLIANCE OR AN OVERNIGHT-ATTENDED PSG (PolySomnoGram-diagnostic sleep test) TO VERIFY THE EFFICACY OF THE TREATMENT.

ALWAYS follow-up with your patient's sleep physician (and any other treating physicians), regarding your patient.

OFFICE PROTOCOL:

Oral Health and Medical Health History Assessment:

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 asthma, breathing, respiratory disorders, or other relevant health problems. Refer the patient to the appropriate healthcare provider for treatment of health problems *before prescribing the appliance.*

IMPRESSIONS:

Impressions of the upper and lower arch including the palate using a high quality alginate or polyvinyl siloxane (PVS) material. We recommend that models be poured in your office in yellow stone, evaluated for defects, trimmed and dried before shipping to the laboratory.

INTRAORAL SCANS:

SML accepts intraoral scans and bites for appliance fabrication. Please visit www.SMLglobal.com/digital-services for additional information.

BITE RECORDS:

A construction bite record is necessary for the dental laboratory to construct an appliance that positions both arches in the proper relationship to one another. Record this relationship (in the patient's mouth) with a hard wax or elastomeric material.

The following steps are recommended:

- **Use an Andra™ or George™ Gauge** to measure the range of motion of the mandible along its anterior-posterior travel. [Both gauges are available from SML® (1-800-423-3270) or www.SMLglobal.com.]
- **Set the gauge** at a fixed position, approximately 70% protruded from the most retruded position. NOTE: The 70% protruded position is a widely accepted starting point for therapy. Patient comfort and appliance efficacy will guide you in adjusting the protrusion of the mandible to the optimal treatment position at subsequent visits.

If your patient cannot comfortably advance to 70%, take the bite record at the most comfortable protruded 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 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.

IMPORTANT: 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.

SHIPPING THE CASE:

Models and bite records should be wrapped separately with bubble wrap and shipped to our certified laboratory with a prescription for the appliance. Prescriptions and mailing labels are available at www.SMLglobal.com.

PATIENT FITTING:

Prior to seating, the new appliance should be properly washed and disinfected with Cavicide®, in accordance with that manufacturer's instructions. Spray Cavicide® directly on the pre-cleaned appliance, thoroughly wetting all sides. Allow the surface to remain visibly wet for 3 minutes at room temperature. Rinse thoroughly.

The delivery visit should confirm the fit and comfort of the appliance, as well as the patients' ability to insert and remove the appliance properly and without difficulty. It may be necessary to adjust the clasps to achieve a comfortable level of retention.

NOTE: The Patients' Directions for Use MUST be dispensed and reviewed with the patient at this visit.

INSERTION:

1. Seat the upper appliance first by gently pressing it up into place with your thumbs.
2. Place the lower appliance against the upper appliance. Then bring the patients mandible forward and carefully seat the lower appliance by pressing down with forefingers to finish the seating of the appliance.

The patient 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.

REMOVAL:

1. Remove the lower appliance first, using thumbs on both sides to carefully lift it off the arch.
2. Remove the upper appliance by carefully pulling down on the sides of the appliance with fingers.
3. Rinse and clean the appliance.

AFTER USE:

Some patients may feel that teeth do not occlude properly. Restore the patients bite relationship by using the SML® Good Morning Positioner (included with every sleep case from SML).

ADJUSTMENTS MADE BY DENTISTS OR PATIENT

Turning the hex driver clockwise to advance the mandible in .25mm increments.
Turning hex driver counterclockwise decreases advancement in same increments.



¼ mm advancement – Turn the Hex Driver clockwise 180° i.e. one-half turn

½ mm advancement – Turn the Hex Driver clockwise 360° i.e. one full turn

1 mm advancement – Turn the Hex Driver clockwise 720° i.e. two full turns

PLEASE NOTE:

1. All Oasys Herbst Hinges are preset with 2mm pre-activation permitting up to 2mm retrusion, if necessary.
2. 3/16" vertical elastics are included if required. These elastics help keep the upper and lower arch together causing a "lip seal". Place the elastic on hook in the upper cuspid area of appliance down around the lower retention screw..
3. Use the Hex Driver to periodically assure that the screws attaching the Hinges to the appliance are tight.

FOLLOW-UP/ADJUSTMENT VISITS:

Schedule follow-up visits to ensure that the appliance is comfortable and effective and that no dental problems have developed.

If additional mandibular advancement is necessary, adjustments may be made while patient is wearing the appliance or have the patient remove their appliance. Be sure to advance the appliance bilaterally and record the millimeters of adjustment made.

Week 1: "Comfort Check." Make any necessary adjustments for the fit and positioning. Adjustments are usually made in increments of 0.5mm

Months 1, 2, and 3: Evaluate teeth and appliance. Make any necessary adjustments.



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Item # 63250PS



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CLINICAL INSTRUCTIONS FOR USE:

ADJUSTABLE HERBST APPLIANCE - OASYS HINGE DUAL LAMINATE

The **Adjustable Herbst Appliance-OASYS Hinge-Dual Laminate Appliance** is fabricated with a soft polyurethane inner liner and a hard copolyester outer layer. The appliance is retained by engaging the buccal and lingual height of contour of the patient's natural undercuts. Retention cannot be modified to accommodate new restorations or loss of posterior teeth. Elastic hooks are included on the upper portion of the appliance so that vertical elastics can be used to maintain a comfortable closed mouth posture if the patient is a mouth breather.



CONTRAINDICATIONS

This appliance is contraindicated if the patient:

- Has Central Sleep Apnea (CSA)
- Has severe respiratory disorders
- Has loose teeth or advanced periodontal disease
- Is under 18 years of age
- Is edentulous or insufficient number of teeth to retain the appliance
- Has inadequate mandibular range of motion
- Has myofacial dysfunction
- Has arthropathy of the TMJ
- Is undergoing any type of orthodontic treatment
- Is undergoing dental work that requires temporary crowns

WARNINGS

Use of the appliance may cause:

- Tooth movement
- Changes in occlusion
- Gingival irritation or dental soreness
- Pain or soreness of the TMJ or facial muscles
- Increased salivation
- Loosening and/or dislodging of restorations

NOTE: A small percentage of patients actually increase their number of apneic and hypopneic events when using an oral appliance. **Should your patients experience any of these adverse events, instruct them to discontinue use of the appliance and call your office.**

PRECAUTIONS:

- Upon removal of the appliance, many patients may feel that their teeth do not occlude properly.
- Performance may be adversely affected by: weight gain, obesity, alcohol consumption, sedative use, allergies, smoking, very high altitudes, increased age, hormonal changes such as menopause, a cold, or sickness that compromises nasal breathing.

IT IS ESSENTIAL THAT THE PATIENT BE TESTED WITH A HOME SLEEP TESTING APPLIANCE OR AN OVERNIGHT-ATTENDED PSG (PolySomnoGram-diagnostic sleep test) TO VERIFY THE EFFICACY OF THE TREATMENT.

ALWAYS follow-up with your patient's sleep physician (and any other treating physicians), regarding your patient.

OFFICE PROTOCOL:

Oral Health and Medical Health History Assessment:

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 asthma, breathing, respiratory disorders, or other relevant health problems. Refer the patient to the appropriate healthcare provider for treatment of health problems *before prescribing the appliance.*

IMPRESSIONS:

Impressions of the upper and lower arch including the palate using a high quality alginate or polyvinyl siloxane (PVS) material. We recommend that models be poured in your office in yellow stone, evaluated for defects, trimmed and dried before shipping to the laboratory.

INTRAORAL SCANS:

SML accepts intraoral scans and bites for appliance fabrication. Please visit www.SMLglobal.com/digital-services for additional information.

BITE RECORDS:

A construction bite record is necessary for the dental laboratory to construct an appliance that positions both arches in the proper relationship to one another. Record this relationship (in the patient's mouth) with a hard wax or elastomeric material.

The following steps are recommended:

- **Use an Andra™ or George™ Gauge** to measure the range of motion of the mandible along its anterior-posterior travel. [Both gauges are available from SML® (1-800-423-3270) or www.SMLglobal.com.]
- **Set the gauge** at a fixed position, approximately 70% protruded from the most retruded position. NOTE: The 70% protruded position is a widely accepted starting point for therapy. Patient comfort and appliance efficacy will guide you in adjusting the protrusion of the mandible to the optimal treatment position at subsequent visits.

If your patient cannot comfortably advance to 70%, take the bite record at the most comfortable protruded 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 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.

IMPORTANT: 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.

SHIPPING THE CASE:

Models and bite records should be wrapped separately with bubble wrap and shipped to our certified laboratory with a prescription for the appliance. Prescriptions and mailing labels are available at www.SMLglobal.com.

PATIENT FITTING:

Prior to seating, the new appliance should be properly washed and disinfected with Cavicide®, in accordance with that manufacturer's instructions. Spray Cavicide® directly on the pre-cleaned appliance, thoroughly wetting all sides. Allow the surface to remain visibly wet for 3 minutes at room temperature. Rinse thoroughly.

thoroughly wetting all sides. Allow the surface to remain visibly wet for 3 minutes at room temperature. Rinse thoroughly with high quality potable water.

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. **NOTE: The Patients' Directions for Use MUST be dispensed and reviewed with the patient at this visit.**

INSERTION:

1. Place the upper part in the patient's mouth and gently press it up into place with your thumbs.
2. Place the lower part of appliance against the upper part and bring mandible forward so the patient can carefully insert their mandibular teeth into the lower appliance.
3. Complete placement by pressing down with forefingers to finish the seating of the appliance.

The appliance is designed to allow the mandible freedom of movement side-to-side, vertically, and protrusively.

REMOVAL:

1. Remove the lower part of appliance first, using thumbs on both sides to carefully lift it off the teeth.
2. Remove the upper part of appliance by carefully pulling down on the sides of the appliance.
3. Rinse and clean the appliance

AFTER NIGHTTIME USE, (and removal of the appliance), some patients may feel that teeth do not occlude as before. If this persists for twenty minutes after removal, patients should be instructed to use the SML® Good Morning Positioner to restore their customary bite relationship. This is accomplished by:

- Placing it between the upper and lower teeth
- Biting down slowly
- Holding this closed position for several seconds
- Repeating until bite again feels normal.

ADJUSTMENTS MADE BY DENTISTS OR PATIENT

Turning the hex driver clockwise to advance the mandible in .25mm increments.
Turning hex driver counterclockwise decreases advancement in same increments.

¼ mm advancement – Turn the Hex Driver clockwise 180° i.e. one-half turn
½ mm advancement – Turn the Hex Driver clockwise 360° i.e. one full turn
1 mm advancement – Turn the Hex Driver clockwise 720° i.e. two full turns

PLEASE NOTE:

1. All Oasys Herbst Hinges are preset with 2mm pre-activation permitting up to 2mm retrusion, if necessary.
2. 3/16" vertical elastics are included if required. These elastics help keep the upper and lower arch together causing a "lip seal". Place the elastic on hook in the upper cuspid area of appliance down around the lower retention screw..
3. Use the Hex Driver to periodically assure that the screws attaching the Hinges to the appliance are tight.

Schedule observation visits to ensure that the appliance is comfortable and effective and that no dental problems have developed.

If additional mandibular advancement is necessary, have the patient remove their appliance in order to make the adjustments. Be sure to advance the appliance bilaterally and record the millimeters of adjustment made.

Week 1: "Comfort Check." Make any necessary adjustments for the fit and positioning. Adjustments are usually made in increments of 0.5 mm

Months 1, 2, and 3: Evaluate teeth and appliance. Make any necessary adjustments in jaw position.

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**SPACE MAINTAINERS
LABORATORIES**

Item # 63250SLS

CAUTION: Federal law requires a written prescription, signed by a licensed medical professional.

CLINICAL INSTRUCTIONS FOR USE: ADJUSTABLE HERBST - OASYS HINGE SLIMLINE (PRESSURE MOLDED)

The **SlimLine Herbst** is fabricated from unbreakable pressure-molded material that finishes with a 2mm thick base. This design provides maximum tongue volume, exposes the incisal edges while supporting all anterior, and has bilateral occlusal blocks that are easily equilibrated even if a very specific wax Construction Bite is not included with the working models.

Elastic hooks are included on the upper portion of the appliance so that vertical elastics can be used to maintain a comfortable closed-mouth posture if the patient is a mouth breather.

CONTRAINDICATIONS

This appliance is contraindicated if the patient:

- Has Central Sleep Apnea (CSA)
- Has severe respiratory disorders
- Has loose teeth or advanced periodontal disease
- Is under 18 years of age
- Is edentulous or insufficient number of teeth to retain the appliance
- Has inadequate mandibular range of motion
- Has myofacial dysfunction
- Has arthropathy of the TMJ
- Is undergoing any type of orthodontic treatment
- Is undergoing dental work that requires temporary crowns

WARNINGS

Use of the appliance may cause:

- Tooth movement or changes in the dental occlusion
- Gingival irritation or dental soreness
- Pain or soreness of the TMJ or facial muscles
- Increased salivation
- Loosening and/or dislodging of dental fillings or crowns.

NOTE: A small percentage of patients actually increase their number of apneic and hypopneic events when using an oral appliance. **Should your patients experience any of these adverse events, instruct them to discontinue use of the appliance and call your office.**

PRECAUTIONS:

Remind patients of the following

- After removal of the appliance after nighttime use, patients may feel that their teeth do not occlude as before. If this feeling persists for twenty minutes after removal, they may use the SML® Good Morning Positioner.
- Be sure the trays are kept clean. Examine them often for signs of wear and tear. If you suspect that damage has occurred, contact SML for possible repair.
- Performance may be adversely affected by: weight gain, obesity, alcohol consumption, sedative use, allergies, smoking, very high altitudes, increased age, hormonal changes such as menopause, a cold, or sickness that compromises nasal breathing.

IT IS ESSENTIAL THAT THE PATIENT BE TESTED WITH A HOME SLEEP TESTING APPLIANCE OR AN OVERNIGHT-ATTENDED PSG (PolySomnoGram-diagnostic sleep test) TO VERIFY THE EFFICACY OF THE TREATMENT.

ALWAYS follow-up with your patient's sleep physician (and any other treating physicians), regarding your patient.

OFFICE PROTOCOL:

Oral Health and Medical Health History Assessment:

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 asthma, breathing, respiratory disorders, or other relevant health problems. Refer the patient to the appropriate healthcare provider for treatment of health problems *before prescribing the appliance*.

IMPRESSIONS:

Dental impressions should be taken of the upper arch and palate and the lower arch using a high quality alginate such as Kromopan® or polyvinyl siloxane (PVS) impression material. We recommend that models be created in your office from the impressions, evaluated for defects, trimmed and dried before shipping to the laboratory.

IMPORTANT: Accurate working models are extremely important for the fabrication of the Slim-Line Herbst. The thin pressure-molded material used for the base of the appliance is exceptionally strong and provides excellent retention extending 1mm to 2mm beyond the height of contour. Adjustments are limited due to the finishing thickness of the material. If we are provided with accurate models, the appliance fit, comfort, and retention will be excellent (requiring no chairside adjustments). We return the models with the finished appliance to demonstrate their excellent fit.

BITE RECORDS:

A bite record is necessary for the dental laboratory to construct an appliance that positions the jaws in the proper relationship to one another. Record this relationship (in the patient's mouth) with a hard wax or elastomeric material. The following steps are recommended:

- **Use an Andra™ or George™ Gauge to measure** the range of motion of the mandible along its anterior-posterior travel. [Both gauges are available from SML® (1-800-423-3270) or www.SMLglobal.com.]
- **Set the gauge** at a fixed position, approximately 70% protruded from the most retruded position. NOTE: The 70% protruded position is a widely accepted starting point for therapy. Patient comfort and appliance efficacy will guide you in adjusting the protrusion of the mandible to the optimal treatment position at subsequent visits.

If your patient cannot comfortably advance to 70%, take the bite record at the most comfortable protruded 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 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.

IMPORTANT: 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 wrapped in bubble wrap and sent with the models to the lab.

SHIPPING THE CASE:

Models and bite records should be wrapped separately with bubble wrap and shipped to our certified laboratory with a prescription for the appliance in the box.

PATIENT FITTING:

Prior to patient contact, the new appliance should be properly washed and disinfected with Cavicide®, in accordance with that manufacturer's instructions. Spray Cavicide directly on the pre-cleaned appliance,