The Luco Hybrid OSA Appliance®
(K130797)

PRESCRIBER INFORMATION
This Manual Contains Important Information
For the Prescribing Dentist

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PREAMBLE:
The following is a step by step guide on the procedure for constructing, fitting, titrating, locking and monitoring a Luco Hybrid OSA Appliance for one of your patients. This appliance is the culmination of over 10 years of clinical research, over 26 years of experience in treating sleep apnea and 28 years of treating TMD. This appliance was developed after experiencing recurrent failures in OSA appliances commercially available. While they would work well for some, others would break and fail within months. Some of the original Luco Hybrids were placed close to ten years ago and are still working very well. This appliance has been rigorously tested and has held up very well.

This appliance is unique among OSA appliances. It has a patented chrome cobalt framework and design, which provides strength and a much reduced size. The chrome cobalt is carried into all high stress areas as a mesh, reducing breakages considerably.

This appliance is one of the new generation that active pharyngeal reflexes to advance the mandible and tongue naturally. This translates into less advancement being needed to open the airway as the tongue and mandible are being positioned by the neuromuscular system of the body.

The forward bite position is also very unique. It places all occlusal pressure in the region of the cuspids and 1st bicuspids. This effectively reduces the occluding forces by up to 75%. It also inactivates the Masseter and medial pterygoid muscles, the muscles primarily responsible for sleep related bruxism.

This appliance is FDA market cleared in the USA for the treatment of mild to moderate obstructive sleep apnea and primary snoring. In Canada, the European Union and Australia, it is approved for these uses as well as in the treatment of sleep related bruxism (when it occurs in the absence of OSA and snoring). This appliance can be used with confidence knowing that it was originally designed over 20 years ago to treat TMD cases, including severe post-traumatic cases. It is still used it for this purpose with excellent results. In the USA, Canada, the EU and Australia, this appliance can also be used under medical supervision for the treatment of severe OSA when the patient cannot tolerate CPAP therapy.

Our website has valuable information you may wish to view. There is an examination form I have developed that includes screening for TMD and OSA and provides a wealth of information when treatment planning these patients. There is an excellent history form which collects important information from the patient and has the Epworth Sleepiness Scale incorporated into it. Please feel free to modify these forms for your practice and your own needs.

I am confident you will be able to achieve the same clinical excellence I have been able to achieve with this appliance.

It is a remarkable fitting appliance that patients are very satisfied with. It does not require extensive adjustment and is a quality treatment for the patient that will last many years.

Sincerely,

Ken Luco BSc, DDS
www.lucohybridosa.com
INDICATIONS/CONTRAINDICATIONS/WARNINGS:

Please read the following important prescribing information before prescribing this appliance:

Indications:
This appliance is designed to treat primary snoring and mild to moderate obstructive sleep apnea in adults.

Risks Associated with Mandibular Advancement Appliances:
Clinical performance testing has shown that this appliance addresses the risks identified within Section 5-Risks to Health of the FDA Guidance Document for Intraoral Devices for Snoring and/or Obstructive Sleep Apnea.

Contraindications for Use:
This appliance should not be used on patients diagnosed with central apnea, have severe respiratory disorders, have loose teeth or advanced periodontal disease or are under 18 years of age. You should not use this appliance if the patient has a known allergy to chrome, cobalt or acrylic.

Warnings:
Use of this device may cause tooth movement or changes in dental occlusion, and may cause gingival or dental soreness. It may cause pain or soreness of the temporomandibular joint. It may cause obstruction of oral breathing and it may cause excessive salivation or dry mouth.

Responsibility:
The prescribing dentist is responsible to ensure that the contraindications, warnings and precautions are considered carefully before prescribing this treatment. Every case must be assessed individually to determine what the best and safest course of treatment is. Care should be exercised when using any mandibular advancement appliance on patients with pre-existing TMJ problems, chronic myofascial pain, fibromyalgia or have a history of chronic neck and back pain as this group of appliances can exacerbate symptoms for some of these patients. Patients who are claustrophobic may not tolerate this or any oral appliance therapy.

HISTORY AND EXAMINATION:
The patient should complete a history of their general health as well as regarding their sleep condition. Questions should include their history of headaches, traumas such as sports injuries to the head and neck, motor vehicle accidents etc. as these patients likely have a concurrent neuromuscular condition with their sleep disorder. TMD, Chronic Myofascial Pain and Fibromyalgia all affect how you will go about treating their sleep disorder. Diabetes and hypothyroidism both are associated with neuromuscular problems and must be considered.

Once you have review the patient’s history with the patient (and maybe their spouse as well), you are ready to examine the patient. You should have a dedicated form to record your OSA examination to ensure consistency in your exams as well as to ensure all pertinent information is recorded. On our website you will find a downloadable PDF examination and patient history forms that screen for malocclusion, neuromuscular problems, internal derangements of the TMJ, CR/CO Slides (and predicting when the patient will have difficulties returning to their normal bite in the morning) and patients that brux.
IMPRESSIONS:
Take full arch silicone or vinyl Polysiloxane impressions. High quality alginate impressions may be used but they must be exceptional. Orthodontic alginate tears less than standard and may be used. Check for the usual impression problems that may occur and retake if not 100% satisfied. Digital impressions may also be used but a bite registration is required separately.

THE BITE REGISTRATION: (George Gauge used as example, principles apply to other devices)
Record the patient’s protrusive range of motion as follows:
1. The first step is to fit the gauge without a bite fork to the lower incisors ensuring it is stable. Tighten the lower thumb screw to lock the position.
2. Remove and place the appropriate bite fork into the gauge. Ensure you have enough posterior opening to accommodate the appliance.
3. Place the assembled gauge, with the grey upper thumb screw for the free movement of the mandible anteriorly and posteriorly) onto the teeth.
4. Ask the patient to retrace as far as possible and record this number.
5. Ask the patient to protrude as far as possible and record this number.
6. Add the two numbers together. This is your protrusive range. Your starting position is a % of this measurement. Calculate the desired protrusion and lock this value into the gauge.
7. Have the patient position into the guide and inject super-fast setting VPS between the teeth taking care to record all of the teeth.

NOTE: For the Luco Hybrid OSA Appliance, any bite registration technique and starting position can be used. The prescribing doctor determines the optimum starting position for each patient. The George Gauge is only used as an example. The appliance has up to 6mm of advancement allowing progressive titration techniques.

IMPORTANT NOTES ON BITE REGISTRATIONS:
- Make sure to inject enough VPS to fully record all of the teeth. This ensures an accurate mounting of the casts when constructing the appliance.
- Instruct the patient to gently bite. The lower blue bite stick is easily broken if the patient bites hard (it is prudent to have a few spare on hand).
- Make sure that when they are biting, both upper and lower incisors are seated fully into the grooves of the bite sticks. Sometimes patients will open slightly allowing the mandible to open. This would result in a very poor fitting appliance as it would have excessive opening.
- As they say in woodworking, measure twice, cut once. Make sure your protrusive position locked into the device is what you intend it to be.
- Keep the gauge level while the VPS is setting. If it drops, the mandible retrudes, if it raises, it advances.
- Always remember that the bite registration is the most critical step in designing the appliance for patient comfort. By ensuring that your casts and bite registration are accurate, you are ensuring that the appliance you deliver to your patients will be comfortable and effective. After all, they will likely be wearing this device every night for the rest of their life!
Advancement Considerations:

75% advancement has been shown in the research to effectively treat sleep bruxism (with the patented forward bite of this device). Since 80% of sleep bruxism occurs with sleep apnea/UARS and has an occurrence of 16% or more in the population, it often occurs with sleep apnea. When present, sleep bruxism should be treated first, to ensure the patient’s comfort and ensure treatment compliance. If not, jaw, muscle or dental pain can discourage the patient and result in treatment abandonment. Fortunately, a 75% advancement also effectively treats many OSA and UARS patient’s symptoms as well. Once the sleep bruxism has been resolved, the patient can be safely advanced further without recurrence of the sleep bruxism. Patients accept a 75% advancement very well when sleep bruxism is present.

Important Considerations when Treatment Planning OSA:

Always measure the entire range of motion, not just protrusive and wide opening. Left, right and protrusive should be roughly equal. This should be done at the initial examination and all findings well documented.

If left or right movement is much less, there could be a medially displaced disk on the contralateral side of the restriction (left lateral =3, right =8, the right disk is medially displaced. This indicates torn lateral ligaments of the disk. This condition will not respond well to advancement and alternative treatments should be considered (CPAP/NPAP).

If, on protrusive, the mandible consistently deviates to a side, suspect an anterior-medial displacement of the disk on the side it deviates to i.e. a non-reducing closed lock. Again, alternative treatment should be considered.

If the patient is opening less than 38 mm and they demonstrate a hard end feel (pressing down on the mandible feels solid as opposed to having some give), they are a poor candidate for any mandibular advancement oral appliance as this is suggestive of either a serious internal derangement of one or both TMJ or chronic myositis of the masseter, both contraindications for mandibular advancement appliances.
THE PRESCRIPTION:
For the prescription for the Luco Hybrid you can download the prescription form below (Figure 6). You can list customizations such as the patient’s name etc. here. If there are any questionable teeth that should not be clasped for retention, it should be indicated here.

If the patient is a gagger or claustrophobic, the posterior palatal bar can be deleted from the design. If the patient suffers from sleep bruxism, it is recommended to have the posterior palatal bar for strength.

Indicate the date you require the case back for. Please sign the prescription and record your license number as indicated.

Please visit www.lucohbridosa.com for this and other useful forms you can Download and customize as needed.
DELIVERY OF THE APPLIANCE

What Tools You Will Need:

To properly fit and adjust this appliance you will need some basic tools and knowhow. The following (Table 1) is a recommended list of tools you should have on hand for the insertion and subsequent appointments.

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<tr>
<th>Name</th>
<th>Photograph</th>
<th>Where Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examination Kit (mirror, explorer, probe)</td>
<td></td>
<td>For examining the patient.</td>
</tr>
<tr>
<td>Ruler</td>
<td></td>
<td>To measure the patient’s mandibular range of motion</td>
</tr>
<tr>
<td>Bite Registration Forceps</td>
<td></td>
<td>Checking the bite on the pads of the appliance. Used with thick bite paper (red or blue)</td>
</tr>
<tr>
<td>Bird Beak Pliers</td>
<td></td>
<td>Adjusting Ball Clasps, adjusting the lower labial bow retainer wire</td>
</tr>
<tr>
<td>Straight Nose Cone Hand Piece</td>
<td></td>
<td>With a fine acrylic bur, to adjust the bite on the pads to ideal. Used with the bite paper.</td>
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INCORRECT TOOLS/EQUIPMENT

If the pliers are incorrectly oriented, they can nick the wire creating a weak spot that could break over time necessitating the need for repairs and addition costs to the patient. Pliers other than listed above can also damage a wire weakening it. It is worth investing in a set or two of decent orthodontic pliers and setting up dedicated kits for OSA treatment.
This section goes through a step by step guide on the delivery of the appliance to the patient.

1. When you received the appliance, examine it for accuracy.
2. Familiarize yourself with the fit on the casts. If there are missing teeth and tipped molars, there may be a specific line of draw for inserting and removing the appliance.

When the Patient Arrives

1. Demonstrate the appliance on the casts for the patient and show them how the upper and lower articulate.
2. Take the upper off the cast, wet in tap water and then place onto the patient’s upper teeth. Gently press the pads onto the teeth. Verify that it seats completely and that there is no rocking. When the patient opens wide, it should not drop. The upper does not need to be very tight as the lower seats it into place during sleep.
3. Check the retention of the upper; it should be comfortably snug on the teeth. The upper does not need to be too tight, only stationary. When both are in the upper is firmly seated by the lower. Adjust the ball clasps slightly and retry. Be careful here, a little goes a long way!
4. To tighten the upper, use Bird beak pliers, place the round beak on the inside where you plan on bending to prevent nicking the wire. Gently bend the clip towards the tooth (green arrow Figure 7). This will bend the ball clasp in and tighten it.
5. Once you are satisfied with the upper, remove by pulling down on the pads of the upper. Set aside.

6. Wet the lower and try in over the lower teeth. Again, check for rocking and retention. Adjust the ball clasps until quite snug. The tongue should not be able to lift it.

7. Try in both together placing the upper first into place. Insert the lower and, with the patient watching in a hand mirror, lift the lower so that the pads are touching and the wings are against the blocks. Then ask the patient to slide their jaw forwards, aligning the lower incisors with the lingual apron and retainer wire, and then instruct them to gently bite to seat the lower. Both appliances should now be comfortably seated and in the treatment position. To remove the lower, have the patient bite together on the pads. While placing a finger under each pad and holding it against the upper, instruct the patient to slowly open and the teeth disengage very easily. The upper is removed with a finger above each pad and gently pulling down.

8. Replace and check the bite on each side. Using thick bite paper, have the patient tap and slide on each side. To remove the lower (as above) and check the markings. There should only be contact on the forward part of the pads equally on both sides. If not, adjust and try in again. In figures 8 and 9, the contacts are not correct. Figure 8 requires the red area to be removed and the right green area to be reduced to ensure the contacts are equal in magnitude. If not, the patient will certainly experience jaw pain and likely a temporal headache upon waking. The contact in Figure 9 is similar, the red area must be reduced until there is equal contact on both sides as in Figure 10.
9. Check the Wing Contacts. Have the patient slide forward and back with the appliance in. Ask them if they feel the wings contacting the adjustment blocks at the same time or if only on one side. If one side has more pressure, this is easily adjusted by advancing the adjustment screw on the side that has less pressure until they are equal (Figure 11). Always advance the side not touching, never retrace the side touching or your desired advancement will be lost.
FOLLOW-UP CARE:
This is a critical part of the patient’s care. They should be recalled and reassessed to ensure that they are improving, complying, as well as to determine at what point they are returned to the sleep lab for a follow-up study.

THE 7 DAY CHECK:
1. Check:
   a. The fit may change due to muscle lengthening (sleep bruxism/OSA patients) and settling of the appliances. You should check
      i. Tightness, is it dislodging in the night? If so, tighten the ball clasps a little
      ii. Have the patient insert and remove them a few times to ensure they are doing it correctly
   b. Check their muscles; the masseter is a very good barometer. If it is relaxed it is likely the others are too. This indicates the reflexes are activated and working and the device is well balanced.
2. Ask the Patient:
   a. Assess their symptoms
      i. Epworth Sleepiness Scale
      ii. Other assessment scale the referring sleep specialist uses
   b. Ask them if they have encountered any difficulties with the appliance and correct
   c. Ask if their spouse reported snoring. If so, they must be advanced.
   d. Ask them if they are waking with a headache or neck pain
3. Adjust the treatment position if needed:
   a. Using a key provided by the lab, turn the screws of the upper adjustment block in the direction of the arrow 2-4 turns (0.5 to 1 mm).
   b. If the patient also has sleep bruxism, and is symptomatic, reset the advancement to 75%, check the bite carefully and check the wings are contacting evenly.
4. Replace both in the patients mouth
   a. Check the bite to be sure everything is still in balance.
   b. Have the patient tap and grind on thick bite paper and go through the steps 2, 3, 4 and 5 again
5. Once satisfied, re-appoint the patient in two weeks

THE 14 DAY CHECK:
Go through all the steps of the 7 day check adjusting and advancing if needed. Re-appoint for the four week check. If they are asymptomatic refer them back to the sleep lab for a sleep study with the appliance in place.

THE 30 DAY CHECK: (if needed)
Go through all the steps of the 7 day check adjusting and advancing as needed. If they are asymptomatic refer them back to the sleep lab for a sleep study with the appliance in place.

NOTE: It is rare that a patient should need to be seen past 14 days. In fact, many patients will not require any advancement from the initial positioning (if 75% is used), it will adequately treat their condition. If you consistently require a longer titration period, please check your technique. You may have skipped an important step. It is unusual to need more than 2 titration appointments. Please retain this instruction manual for future reference. If lost or damaged, a new copy can be obtained from our website.
FINAL ADJUSTMENTS
Once the patient has successfully had their verification sleep study you must see the patient to lock the advancement screws. This prevents slippage of the screws over time and loss of the treatment position.

LOCKING THE ADJUSTMENT SCREWS:
The easiest and effective way to lock the screws is to use a small amount of composite resin and inject it over the adjustment screw ensuring it does not occlude the adjustment screw holes. Do not place bond or other adhesive. IF the patient requires further advancement, simply open the screw and the bonding will fall out. Once the adjustment is made, simply re-inject and cure more bonding at the new position.

CHECK THE BITE ONE MORE TIME
This is the final bite check. Adjust if needed. Re-appoint the patient for 6 to 12 months and instruct them to call if their symptoms return, if they have dental work done that changes the fit, or if they have any discomfort wearing the appliance.

IF THE PATIENT RELAPSES
In the event that the patient gains weight or similar and symptoms return, it is easy to adjust the device. Simply turn the adjustment screw and the composite resin will dislodge. Then you can advance the appliance as needed and simply cure more composite in place.

THE LONG TERM REASSESSMENT/COMMITMENT
The patient should be instructed that 6-12 month reassessments are a necessary part of their treatment. At the reassessment appointment, go over their symptoms, check the fit, and adjust the bite or any other maintenance issue required. Check the patient’s muscles for tension, they should be relaxed. Any headaches associated with myopathy should be gone. They should be well rested and look well. Update their Epworth Score, it should be under 10 and ideally under 5.

Check the appliance for signs of poor home care and bring these to the patient’s attention. Reinforce to the patient that you must follow them over time as the appliance must be monitored. Instruct them to contact you immediately if they feel their symptoms have returned, have dental work done changing the fit or if they cannot wear the appliance. Re-appoint them for their next check in 6-12 months.

NON-COMPLIANCE
A quick and easy test to determine if the patient is wearing the appliance is to ask them to place it into their mouth without a mirror. If they are wearing it regularly, they will have no difficulty doing this. If they are not wearing it, they will fumble with it or mix up the upper and lower components. If this occurs, reinforce to the patient the need for this treatment and your requirement to notify their sleep specialist if they are not wearing the appliance as prescribed. If they seem resistant at this point, it is your responsibility to contact their sleep specialist and notify them of the patient’s non-compliance.

If the patient does not present for follow-up care, it is your responsibility to contact the referring sleep doctor and inform him of a potential compliance problem. Untreated OSA patients are at much higher risk of personal injury due to fatigue, motor vehicle accidents etc. Never forget that the referring doctor is overseeing these cases and must be informed of these situations.

In many regions, there are only a few conditions where a medical doctor can revoke a patient’s driver’s license. They include uncontrolled epileptic seizures, uncontrolled sleep apnea, dementia, loss of vision etc.
Sometimes informing a non-compliant patient of this regulation converts them into a very compliant patient instantly.

We are confident you will find this device very easy to implement into your practice and a pleasure to use. The ability to effectively treat OSA patients who also suffer from sleep bruxism sets this device apart from all others. TMJ and jaw pain are known risks of mandibular advancement appliances and only the Luco Hybrid OSA Appliance® can address these symptoms during OSA therapy effectively ensuring your patients are...

“Sleeping in Complete Comfort®”
**Trouble-Shooting:**

No matter how good your impressions and bites are, there will be instances where something goes unexpectedly and you must find a solution. The following table outlines the most frequent problems, many which relate to sleep bruxism underlying the OSA/UARS.

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>SOLUTION</th>
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<tbody>
<tr>
<td>The patient experiences tooth soreness</td>
<td>Check the bite carefully and query the patient as to which side touches first. Check that you don’t have a ball clasp too tight on a tooth. On the lower appliance, tighten the labial bow and you can sometimes loosen the ball clasps on the bicuspids. ENSURE there is no contact expect the maxillary cuspid/1st bicuspid region. Contact on the molar area will cause jaw pain.</td>
</tr>
<tr>
<td>The patient reports waking with a headache some mornings</td>
<td>There is active sleep bruxism. Reset the advancement to 75%, recheck the bite is even and recheck the wings are contacting evenly. This will stabilize the sleep bruxism rapidly.</td>
</tr>
<tr>
<td>The patient reports a sore jaw in the morning</td>
<td>Check their masseter muscles and then re-check the bite carefully. Especially check there are no molar contacts which will encourage bruxism. Ensure the bite looks like Figure 10. Query the patient: are they chewing a lot of gum? Did they injure themselves biting something hard unexpectedly? Often there is an underlying cause of jaw pain independent of your treatment. Resetting the bite to the patient’s current 75% will often alleviate jaw pain rapidly.</td>
</tr>
<tr>
<td>The patient reports a sore neck on waking</td>
<td>Reset the appliance to 75% advancement as this is clinically shown to reduce neck pain on waking. Query the patient as to what type of pillow they use and how they sleep. Recommending a good RMT or PT in the area is often greatly appreciated. Recommend a “side-sleeper” pillow as this usually is all that they need.</td>
</tr>
<tr>
<td>The patient reports having a very dry mouth at night</td>
<td>Instruct the patient to keep a glass of water by the bed. They can drink without removing the appliance. Suggest Biotene’s products or similar products for xerostomia if the problem persists (sprays are quite effective).</td>
</tr>
<tr>
<td>The patient drops the appliance and bends a labial bow (very hard to do)</td>
<td>If you are a proficient wire bender you might be able to undo this. Or you can take new impressions and send it to your lab for repair. It is near impossible to know exactly where the wire was distorted and often this is the best option.</td>
</tr>
<tr>
<td>The tongue is sore on the side(s) in the morning</td>
<td>This is usually caused by the lower appliance lifting during sleep and the patient biting it. Tightening the ball clasps is usually all that is needed.</td>
</tr>
<tr>
<td>The lower lifts up when the patient opens their mouth wide</td>
<td>If you have advanced the appliance 3-4mm ahead of the 75%, the curve in the wing should be removed. If not, the pressure on the wing can dislodge the lower appliance in some cases.</td>
</tr>
</tbody>
</table>

These are the most common (and actually not that common) concerns patients may present with and How to solve them.

If you have questions not answered in this manual, please contact the lab that made the device for you. They have advanced training in the device and can usually answer your inquiries. If you still have questions, you can contact Dr. Luco directly at the email listed below, by mail, or by fax. There is also a contact form on our website you may use (www.lucohybridosa.com).