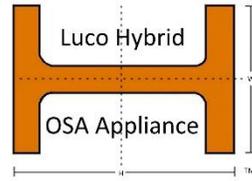


By Rx Only



The Luco Hybrid OSA Appliance[®]

Sleeping in Complete Comfort[®]

Patient Manual

The Luco Hybrid OSA Appliance®

Important Information: Please Retains this for Future Reference

Congratulations on receiving your new appliance. This manual contains important information about your appliance and we recommend that you retain this manual for future reference.

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Glossary of Terms:

<i>Obstructive sleep Apnea (OSA)</i>	When the tongue falls back and the muscles of the throat relax during sleep, they can block the airway. This is termed obstructive sleep apnea.
<i>Snoring</i>	When the tissue of the throat vibrates during breathing in, a loud noise can be produced. This is termed snoring.
<i>Sleep bruxism</i>	During sleep, the teeth are clenched or ground side to side with up to ten times your normal biting force. This is termed sleep bruxism.
<i>Pharyngeal reflexes</i>	These are reflexes that, when stimulated, either move the tongue and lower jaw forward or prevent them from being pulled back.
<i>Mandibular advancement</i>	This appliance holds the lower jaw forward or advances it. This opens the airway, repositions the tongue and relaxes the jaw muscles.
<i>TMJ</i>	This is your jaw joint, located just ahead of your ear canal.

Indications for use:

This appliance is designed for the treatment of mild to moderate obstructive sleep apnea, primary snoring, sleep bruxism and to aid in the treatment of tension / migraine type headaches in adult patients.

Description of the appliance:

The Luco Hybrid OSA Appliance[®] is a two part (upper and lower) mandibular advancement type appliance. It has a cast metal (chrome cobalt) framework and acrylic biting surface. The appliance works by a wing/block system where the lower appliance's wing engages the upper appliance's block to hold the lower jaw in a forward positioning.

The metal framework provides strength while reducing the material on the inside of the mouth (preserving space for the tongue). There is no acrylic in the front of the mouth allowing mouth breathing as needed. The tongue can rest in normal position without restriction.



What this appliance does and how it works:

This appliance is designed to hold the lower jaw forward. As the tongue is attached to the lower jaw, it moves forward as well. This results in opening up of your airway allowing air to more easily pass through. This also reduces snoring as the tongue is ahead of the soft palate reducing vibration and noise. The forward bite only allows contact at the upper eyetooth region of the appliance. This reduces the force that the muscles can generate reducing the strain on the teeth, supporting bone, muscles and TMJ caused by sleep bruxism.

Risks assessment with mandibular advancement appliances:

There are inherent risks associated with this group of appliances that have been identified over the year with other similar appliances. Through extensive clinical testing on over 2500 patients followed over a twelve year period, the Luco Hybrid design addresses the risks identified in Section 5 –Risk 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 you have a known allergy to chrome, cobalt or acrylic. This cannot be used on patients who do not have teeth (wear full dentures). Patients with serious TMJ problems such as non-reducing closed locks or TMJ prostheses (artificial joints) should not use this appliance.

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.

Instructions on use:

The upper appliance is always placed first, as it is further back. Wet the appliance under tap water then place in your mouth orienting the retainer wire over your front teeth and the pads over the back teeth. Gently push it to place until it seats against the teeth. There should be no rocking and it should feel solid on the teeth.

Wet the lower appliance under tap water and then place into your mouth orienting the retainer wire forward. Push the appliance up so that the lower pads are contacting the upper pads and the wings of the lower appliance are contacting the blocks of the upper. Slide your jaw forward aligning it into the lower appliance. It is important to check that your jaw is correctly positioned in the lower. Once it is, gently bite into the lower and it will seat into position. The appliance is now in its treatment position and holding your jaw and tongue forward.

For the first few days, you may want to put the appliance in an hour before going to bed, to help you get used to the feel of it. Then remove it, floss and brush your teeth and replace it. Your muscles and jaw will be used to the position and it will be easier to fall asleep. Please remember that it could take a day or two for you to get used to the appliance and for it to really start working. Everyone is different so please be patient.

To remove the appliance in the morning, place a finger under each side of the lower appliance in the pad regions. Press the lower appliance up against the upper appliance (the treatment position) snugly. While doing this, open your mouth and your lower teeth will separate from the lower appliance easily. Remove the lower appliance from your mouth and set it in a safe place. To remove the upper, slide a finger on each side up above the pads of the upper. This may be easier if you do not open wide while doing this. Once your fingers are in place, gently push down on the pads and the upper appliance will drop down. Remove it and place it with the lower. Clean both immediately and place into their storage case in a drawer to protect them. If you have pets, be sure to store this safely where they cannot reach it.

When and why to wear your appliance:

Your appliance must be worn every time you sleep, even if only for a nap. Sleep apnea has been linked to many medical diseases, such as enlargement of the right ventricle (chamber) of the heart, heart attack, sudden death, silent strokes and Type II diabetes and recently some types of cancer. Sleep bruxism can seriously damage your teeth and supporting structures. Please remember that sleep bruxism is unconscious, you cannot control it. Your appliance will protect your teeth from its effects. Wearing the appliance whenever you sleep can significantly reduce the symptoms associated with sleep bruxism as well as preventing damage to your teeth, jaw bone, muscles and TMJ.

Cleaning and caring for your appliance:

For cleaning your appliance we recommend a liquid soap (either hand soap or dish soap) and a soft toothbrush that you dedicate for this purpose. Liquid soap does not scratch the surface of the acrylic whereas toothpaste, being slightly abrasive, will. These tiny scratches can harbor bacteria and cause your appliance to take on an odor. If you clean with liquid soap, this will not happen. Once a week you can use a commercial denture cleaner as long as it states it is safe for partial dentures and orthodontic appliances. There are a number of these available and any will do. Do not soak longer than 15 minutes as this can damage the appliance. This will keep the appliance fresh and clean and disinfects it regularly.

If you have a flu or infectious illness, you should soak the appliance in the commercial cleaner, once you are feeling better, to disinfect it (be sure it is safe for orthodontic appliances or partial dentures). Discard the soft tooth brush and replace it with a new one as the old one is contaminated. You should clean your case as well. The storage case may be cleaned and with soap and water as well and should be done at least weekly to prevent bacteria from growing and causing an odor.

NEVER CLEAN YOUR APPLIANCE WITH BLEACH or it will permanently damage your appliance.

Storage:

Once you have removed and cleaned your appliance, place it in its storage case immediately. Never leave it out loose on a night table or bathroom counter as it could get knocked off and damaged or something heavy placed on it and distorted. The case is ventilated (has holes in it) to allow the appliance to dry between uses. This is important as you should not store your appliance in water or other cleaning solution or it will be damaged. It is designed to dry between uses. If you have family pets, be sure to place the appliance, in its case, inside a cupboard or drawer where the pet cannot get at it. Pets will chew the case to get at the appliance and will chew the appliance either damaging appliance or themselves in the process. The same is true for young children; they are very curious and will try to copy their parents. This is a medical device and must be kept in a safe place. Never leave your appliance, even in the case in a hot car or in the sun as excessive heat can damage the acrylic of the appliance permanently.

Other Important Information:

This treatment must be monitored. Your dentist, once fitting you with your appliance, will bring you back in for reassessments. This is very important so he/she can check the fit and make necessary adjustments as needed.

In the case of sleep apnea or snoring, once he/she has completed the adjustments and your symptoms have improved, they will contact your sleep specialist for a post treatment sleep study with your appliance in. This will ensure you are getting the maximum benefit from your treatment. In some cases, the second sleep study might recommend further adjustments. These are easily done by your dentist.

For sleep bruxism, your dentist will monitor your progress until you are comfortable. He/she may conduct a home EMG (muscle) sleep test to record your muscles while sleeping, to ensure the appliance is working correctly. It is critical that you see your dentist at least once a year to check this appliance and ensure it is fitting correctly and working as intended.

Never adjust your appliance yourself or you could damage it or cause serious injury to yourself. Your dentist is trained in the use of this appliance and the best person to adjust it properly.

It is critical that you follow your dentist's recommendations as unsupervised treatment can result in serious complications. It is in your best interest to follow all instructions carefully to ensure you obtain the maximum benefit from your appliance/treatment.

Dental Work After You Have Your Appliance:

If you have dental work done, the appliance will likely need to be adjusted to the new work. This is easily done and will return your appliance to its previous fit. If you lose a tooth, it often doesn't affect the fit. If you lose a few teeth, it may require replacing one or both parts of the appliance. Speak to your dentist about this and he/she can best advise you of your options.

What to Expect for the Lifespan of Your Appliance:

If you follow the recommendations in this document for caring for your appliance, your appliance should last between 3 to 5 years. At that time, if the fit is still good, your dentist can send your appliance in and replace all of the acrylic on it. This design is such that the framework, as long as you don't lose teeth or have extensive work done, can be reused many times. The acrylic can be replaced over and over again without damaging the framework by a qualified lab (this type of work should only be done by a lab certified in making the Luco Hybrid OSA Appliance®).

Some patients, after 4-5 years of wear, elect to have a new appliance made and keep the old one as a spare. Many insurance carriers will replace these appliances every 3-5 years (the normal lifespan of most appliances) and this entitles you to a brand new one. Having a spare is comforting. Should your appliance have to be sent in to be refit to new dental work, you are not left untreated.

Sleep bruxism is a very destructive process. This appliance is clinically shown to withstand and control the effects of this sleep disorder. The lifespan reflects the effectiveness of this device.

Troubleshooting:

The following are some of the possible problems we have seen clinically and how to remedy them:

The Concern...	The Cause...	The Solution...
My appliance smells bad or taste bad	The appliance has bacterial growth on it.	Soak as directed in a commercial denture cleaner. Make sure you clean it as directed after every use.
My teeth or jaw are sensitive on one side on waking	Your bite is heavier on one side on the appliance causing more pressure	See your dentist for an adjustment of the bite
My back teeth don't touch in the morning	This is normal for this group of appliances. The muscles are stretched and relaxed and try to maintain the appliance position (muscle memory). Patients with deep overbites will experience more of this effect.	You should wait 15-30 minutes before eating in the morning while gently biting together. If it is a problem, see your dentist and he/she can make you a morning appliance that aids in resetting your bite back to normal
My lower appliance is lifting up in the night	The clips or retainer wire have loosened. Be sure to remove it as instructed to prevent bending of the clips and wires	See your dentist for an adjustment. The clips or retainer wire need adjusting
I have a hard time falling asleep at night	This can be caused by caffeine within 8 hours of sleeping, stress and your mind racing, fighting the appliance, poor sleep habits and many other things.	Do not have caffeinated beverages within 8 hours of sleeping. Put your appliance in an hour or two before bed. This will get your mouth and muscles used to the appliance and it will not affect you falling asleep. Try to get onto a routine for sleeping. The same time every night, your bed is for sleeping, not for TV or reading.
I have excessive amounts of saliva when I wear the appliance	The appliance is stimulating saliva production.	This is normal at the start but normally subsides within the first week. Avoid chewing gum for a while, this may help. Gum also is a salivary stimulant and if you chew it in the evening, it could be a cause.
I have a dry mouth when I wear the appliance	<i>This occurs frequently all of these appliances. This is due to the lips not sealing when you are sleeping. Sometimes this is inevitable, other times it resolves. Some dry mouth is due to side effects of medications being taken.</i>	<i>Keep a glass of water near your bed. You can drink water without removing the appliance. There are also sprays and lozenges available at pharmacies for dry mouth problems that can help. Talk to your pharmacist about this.</i>
My jaw muscles are sore in the morning	The bite may due to an uneven bite resulting in muscle activity while sleeping. Some people have genetic conditions or post-traumatic injuries that respond negatively to this type of treatment.	See your dentist for a bite adjustment. Also, your dentist provided you with some exercises to do for this when he/she delivered your appliance. Make sure you do these daily at night and in the morning. They help.
My jaws get sore during the day now and they didn't used to	Your normal bite is not ideal and the position of the appliance is more comfortable. You may have an underlying medical problem affecting your muscles.	Make sure you do the exercises you were given by your dentist to do. This will strengthen your muscles. Maintain a healthy diet to ensure you are getting a balanced diet. Do not chew gum.

Company Information:

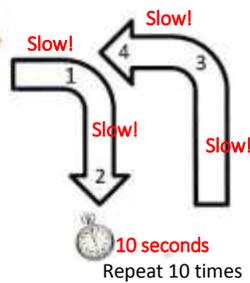
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EXERCISES FOR JAW DISCOMFORT

When first starting treatment, the jaw muscles can resist the change in jaw position, especially with moderate to severe sleep bruxism. The following exercises may be used to reduce any discomfort as needed. They may be repeated 3-4 times per day as required.



Jaw Mobility Exercise:

1. Slide your lower jaw forward
2. With the jaw forward open as wide as comfortable and hold for a count of 10
3. Keeping jaw forward, slowly close
4. Slowly slide the lower back into the bite



Resisted Opening Exercise:

1. Place your fist under your Chin
2. Open separating your teeth a few millimeters
3. Push down with your jaw but resist it with your fist
4. Your mouth should not open more than a few mm
5. Push down firmly while resisting with your fist

10 seconds
Repeat 10 times

Please Note:

Minor jaw pain is normal at the start as your muscles adjust to the new positioning. If you have persistent jaw pain or jaw pain that is worsening with time, please contact us for an appointment.