Informed Consent for Mandibular Advancement Devices for Patients.

Obstructive Sleep Apnea (OSA) and snoring are respiratory disorders that occur repeatedly during sleep due to the total obstruction (Apnea) or narrowing of the respiratory airway caused by the position and tension of the muscles involved in the passage of air through the upper airway. The main symptoms of Obstructive Sleep Apnea are snoring, respiratory pauses during sleep, daytime sleepiness, fatigue, etc. OSA can pose serious health risks as it alters normal sleep patterns and can reduce normal blood oxygen levels. This condition can increase the risk of daytime sleepiness, fatigue, headaches, traffic and work accidents, hypertension (high blood pressure), heart disease, strokes, diabetes, obesity, memory and learning problems, and depression.

There are several treatment alternatives:

- Continuous Positive Air Pressure Device (CPAP).
- Mandibular Advancement Devices (MAD).
- Pharyngeal orthognathic surgery or upper airway surgery.
- Positional therapy during sleep.

In any case, it is recommended to carry out hygienic and dietary measures of which I have been informed.

This informed consent refers to the treatments with MAD by OrthoApnea.

The therapy with MAD for OSA and snoring aims to facilitate breathing by keeping the tongue and jaw in a forward position during sleep hours. MADs are clinically tested and have high effectiveness, however, there are no guarantees that it will be effective for you. Each patient's case is different, and there are many factors that influence the upper airway during sleep. It is important to recognize that even when the therapy is effective, there may be a period of time in which you experience symptoms related to your sleep respiratory disorder. For this, several follow-up visits may be necessary in which mandibular advancement adjustments are made.

A polygraphy or polysomnography (sleep study) can be performed after the adjustment to objectively ensure the efficacy of the treatment. You should request it from your doctor. MADs are indicated for patients with mild to moderate obstructive sleep apnea and severe cases intolerant to other treatments. It is also indicated for snoring patients. Its use is contraindicated in patients with central sleep apnea, other respiratory diseases, advanced periodontal problems, and in patients under 18 years of age.

It is a type of reversible treatment, that is, it is only effective when placed in the mouth and can be stopped at any time (unlike surgical treatment). If not used, you will return to having the symptoms of OSA and/or snoring.

SIDE EFFECTS OF MADS. Scientific studies published show that the short-term side effects of treatment with MAD can include excessive salivation, difficulty swallowing (with the device placed), jaw or tooth pain, jaw joint pain, dry mouth, gum pain, dental movement, and short-term bite changes. Most of these side effects are minor and resolve quickly on their own or with a small adjustment of the device.

There are also studies on the misfit of dental restorations (crowns, implants, etc.). Long-term complications include changes in the bite that, in some cases, may be permanent as a result of tooth movement or repositioning of the jaw joint. These complications may or may not be fully reversible once oral appliance treatment is discontinued. If they are not reversible, restoration treatment or orthodontic intervention may be necessary, for which you will be responsible.

Follow-up visits with your sleep specialist are mandatory to ensure the correct adjustment of the device and the effectiveness of the treatment. If unusual symptoms or discomfort occur that are outside the scope of this consent, or if analgesics are required to manage the discomfort, it is recommended that you stop using the device until further evaluation is made.

In exceptional cases, you may feel nausea, difficulty falling asleep, or swallow part of the device.

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I DECLARE: That I have been informed about OSA, treatment alternatives, treatment with MAD, and the possible side effects in terms of discomfort and complications that may arise from the use of MAD. You are aware that the treatment may not be completely effective for you and that it is your responsibility to report side effects and the evolution of symptoms to your sleep specialist. In addition, you are aware that not treating sleep-related respiratory disorders can increase the likelihood of significant medical complications.

All doubts or questions that have arisen related to the intervention, risks, and complications have been satisfactorily answered and clarified.

I AUTHORIZE: the sleep specialist and their team to take the necessary information (records, measurements, photos, videos, x-rays, etc.) for the realization of your treatment with MAD. I authorize the transmission of the information to OrthoApnea for the design and manufacture of the device. In addition, I authorize all parties to use the collected information for research or scientific dissemination purposes, ensuring at all times the anonymity of my person.

Name: .....

Place and date: .....

Signature:

You reserve the right to revoke this consent, without giving any reason, at any time before the procedure, test or action described above is performed.

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