



Informed Consent for NightLase® Laser Snoring and Sleep Apnea Reduction

Information:

You have a significant snoring issue and if you have been diagnosed with Obstructive Sleep Apnea you either cannot tolerate or choose not to tolerate CPAP or a Mandibular Advancement Device, or are choosing to use this treatment in conjunction with other treatments as a co-therapy. If you do not have a previous diagnosis, we have reviewed with you the medical disorders that may be related such as high blood pressure, weight gain, hormone imbalances, stroke, cancer, and coronary artery disease to name a few. If appropriate we have recommended that you seek medical care for screening for OSA with your medical practitioner/sleep doctor.

Purpose:

This treatment is an alternative procedure for patients who cannot tolerate CPAP and or Mandibular Advancement Devices. Or, has been recommended as a co-therapy/adjunct therapy. NightLase® has been found to be a therapy that is beneficial in reducing snoring and OSA or its side effects by opening the airway. Studies show that NightLase® can reduce snoring by 50% on average. 95.2% of people state improvement in snoring and 57.1% reported significant improvement in snoring after treatment. (Journal of the Laser and Health Academy ISSN 1855-9913 Vol 2013, No.1). CBCT analysis shows an average of 20-22\$ increase in airway volume. (Evaluation of a non-ablative Er:YAG laser procedure to increase the oropharyngeal airway volume: A pilot study. ISSN: 205B-5314.)

Type of Dental Intervention:

Erbium: Yag Laser non ablative (non-cutting) treatment of the soft palate and surrounding area.

Procedure and Protocol:

1. Treatment Consent
2. Photo/Video Consent
3. Pre- Op Photos
4. Fill out pre-treatment evaluation
5. Laser treatment (30-60 min)
6. 3-4 or more repetitions of laser treatment 21 days apart, or as recommended by Dr. Taylor
7. Post Op Photos

A: Unfamiliar Procedure

The intra-oral use of Erbium: Yag Laser.

Post operatively; you may feel a sensation similar to a mild throat irritation for a day or two.

Green City Dental

O: 425-776-3352 F: 425-361-1485 E: lovemyteeth@greencitydental.com
A: 8405 196th St SW Edmonds, WA 98026 W: greencitydental.com

B: Duration

Treatment will consist of three+, 30-60 min sessions 21 days apart.

C: Risks

There are no risks other than that you may not perceive an improvement in your symptoms.

Possible Benefits:

- Improved Sleep Quality
- Reduced Fatigue
- Weight Loss
- Happier Spouse/Family
- Increase in Airway Volume
- Reduction in Sleep Apnea
- Improved Nasal Breathing
- Postural Changes

Length of Treatment

The NightLase® treatment is strictly a therapy to help maintain a more open airway during sleep and daytime hours. It does not cure snoring or sleep apnea. Due to patient variation the treatment may last from 6-12 months and in most cases requires some re-treatment/maintenance. Over time it is possible that snoring can develop into sleep apnea. Sleep apnea may also become worse for many reasons (weight gain, muscle tone gets weaker as we age, hormonal imbalances, pregnancy, etc.) Therefore, it is important to be screened yearly. If unusual symptoms occur, you are advised to schedule an office visit to evaluate the situation.

Individuals that have been diagnosed with having sleep apnea may notice that after NightLase® treatment they feel more refreshed and alert during the day. This is only subjective evidence of improvement of OSA and may be misleading. The only way to accurately measure whether the NightLase® treatment has assisted in keeping oxygen levels sufficiently high to prevent abnormal heart rhythms and other problems is to be retested with a sleep study that is read by a board certified sleep doctor. It is recommended that you wait 60 days after the last treatment before re-testing for sleep apnea or snoring as it can take this long for tissues to fully respond and to see optimal results.

Confidentiality:

All data will be kept confident, only the results will be tabulated or research according to standard protocols.

Risk to Refuse of Withdraw:

You have the right to withdraw before completion of the treatment. Premature withdrawal from treatment and/or lack of compliance will reduce the maximum benefit of treatment outcome and you may not experience any benefit.

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Alternate Treatment

Other accepted treatments for sleep disordered breathing (such as snoring and sleep apnea) include behavior modifications, weight loss, hormonal therapy, myofunctional therapy/frenectomy, surgical procedures, and CPAP appliance/oral appliances. You have chosen NightLase® therapy to treat your particular problem and are aware that it may not be completely effective or as effective for you if not used in conjunction with other treatments.

Pre-Op Recommendations:

Stay hydrated: Drink 1/2 body weight in ounces 1 week prior to treatment.

Avoid excessive alcohol consumption 2-3 days before treatment and avoid smoking cigarettes or marijuana the day of treatment.

Download Snorelab on smart phone and record 3 nights with no intervention, and 3 nights using nose cones, breathe right strips, or mouth tape. Please email results to info@greencitydental.com prior to procedure date. Failure to do this could result in postponing of treatment or alteration of recommended treatment plan.

Do NOT have any dental procedure done 2 weeks before or after treatment.

Usual Occurrences/ Post Op Recommendations:

During the procedure most people feel slight warming or stinging of the tissue, this is normal and means that the treatment is working (yay). Some people feel nothing at all. You may experience a burning smell (this is normal). Gagging may also happen during procedure as we may need to push tongue down to access appropriate tissues.

Once we start the procedure you will not be allowed any bathroom breaks or opportunities to take a break (this is because the tissue needs to stay warm for the treatment to work,) so please take bathroom breaks BEFORE the start of treatment. It is important that you communicate if the treatment is too painful or you wish to discontinue treatment during procedure so we can accommodate your needs.

After the procedure it is normal to feel a slight sore throat or dryness in the tissues. This should only last a few days and does not need further treatment. Coconut oil swishing/gargling can help with any discomfort. You may want to avoid hot and spicy/salty foods after treatment (your own discretion is advised.) Some patients report increased ability to breathe through nose. If this happens and the nose is still partially blocked due to inflammation or physical obstruction, nasal snoring may occur after treatment because of improvement in nasal breathing.

Touch up treatments will be needed yearly or as recommended by Dr. Taylor and the initial cost of treatment does NOT include touch up treatments. NightLase® is not a permanent treatment and because of this typically needs 1-2 treatments yearly to maintain results, or as indicated by Dr. Taylor. Touch up treatment fees are not included in initial treatment pricing and are due at time of service.

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Unusual Occurrences:

As with any form of medical or dental treatment, unusual occurrences can and do happen. Mouth sores, muscle spasms, and sore jaw muscles are all possible occurrences. Most of these occurrences are infrequent. Additional medical and dental risks that have not been mentioned may occur. Good communication before, during, and after treatment is essential for the best treatment results. Please call or come to the office if you have any questions of problems regarding treatment.

Part II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily and understand that I have the right to withdraw from the treatment at any time without in any way affecting my medical care. I consent to the taking of photographs, videos, and any necessary x-rays/exams before, during and after treatment, and their use in scientific papers, demonstrations or discussions of the procedures in social media, print and online. I recognize that my treatment will not be as successful if I do not complete the appropriate number of treatments in the time recommended by Dr. Taylor. I recognize that this is a cosmetic procedure and may alter my cosmetic appearance.

I agree and understand that I am 100% responsible for financial arrangements and that payment for full treatment is needed prior to the start of treatment. Because results may vary, no refund will be given after completion of treatment. I understand that this treatment will most likely NOT be covered my insurance and I am prepared to pay for treatment out of pocket. Any questions regarding insurance or reimbursement will need to be had with your insurance company directly. Green City Dental is not liable for any miscommunication with you and your insurance company and requires payment in full before the start of procedure.

Print Name of Patient: _____

Signature of Patient: _____ Date: _____

Print Name of Witness: _____

Signature of Witness: _____ Date: _____

I have accurately read or witness the accurate reading of the consent form to the potential patient, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Treating Doctor: _____

Signature of Treating Doctor: _____ Date: _____

A copy of this Informed Consent has been provided to the participant _____ (initialed by Dr/assistant)

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