SUBURBAN
Ear, Nose & Throat
Associates, Ltd.

Otolaryngology-
Head & Neck Surgery

Lon J. Petchenik M.D.

George Smyrniotis, M.D.

Glenn J. Schwartz, M.D.

Kirk R. Clark, M.D.

Allan A. Ho, M.D.

Maria L. Wittkopf, M.D.

Marci J. Pugnale, M.D.

Shannon K. Pachnik, FNP-C

Allergy-Immunology

Anne Marie Ditto, M.D.

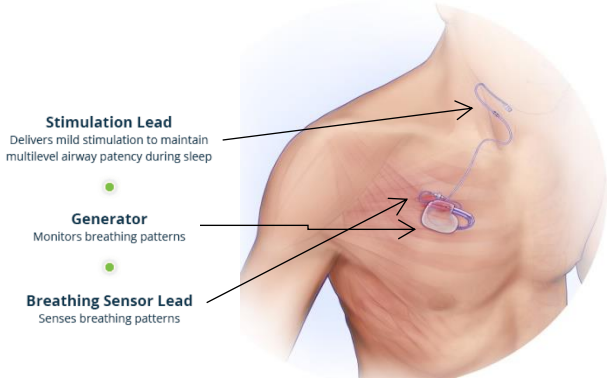
5999 New Wilke Rd
Building 1
Rolling Meadows, IL 60008

1555 Barrington Rd
Doctors Building 1, Suite 530
Hoffman Estates, IL 60169

Telephone: (847) 259-2530
Fax: (847) 259-4930
www.SubENT.com

PLACEMENT OF HYPOGLOSSAL NERVE STIMULATOR FOR OBSTRUCTIVE SLEEP APNEA

Information and Informed Consent



Placement of a Hypoglossal Nerve Stimulator (HNS) is a surgical treatment option for patients with Obstructive Sleep Apnea Syndrome (OSAS) that have not been tolerant of standard options, especially of CPAP (Continuous Positive Airway Pressure) device. Each of the components of the system (Inspire©) are placed via 2 separate incisions/surgical sites, typically on the right side of your neck and chest, and performed simultaneously under general anesthesia. The Breathing Sensor Lead is a small pressure transducer that senses an inhalation. This incision is combined with the Generator incision, implanted in between 2 of the rib cage muscles. This sensor sends a signal to the Generator, which in turn sends an electrical impulse to the Stimulation Lead that was placed around the hypoglossal nerve during the surgery. The Generator incision will be just below the collar bone. The Stimulation Lead is placed with an incision just under the jaw line. The wire between the Stimulation Lead to the Generator,is tunneled under the skin. The lead from the breathing sensor to the Generator comes thru the pectoralis muscle. Each time when you go to sleep, you will remotely turn the system on, and upon awakening for the day you will turn the system off. You can place it on hold for 15 minutes if you get up to use the bathroom or wake briefly. The system will be activated by the sleep lab/sleep medicine physician about 4 weeks after implantation.

SURGICAL RISKS and POSSIBLE COMPLICATIONS:

All surgeries have a small risk of bleeding or infection. You will receive peri-operative antibiotics to minimize the risk of infection as we are implanting foreign material into your body. Although rare, if infection was to occur, it could necessitate removal of the hardware (reported <1%).

There is a risk of needing a reoperation (reported up to 4%) for device or other technical problems.

Several nerves are placed at risk during the surgery: The incision under the jaw line gives access to the region of the hypoglossal nerve. With the incision there is a small risk of injury to the Marginal Mandibular Nerve that supplies function

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to the muscles at the corner of your lip. If injury was to occur there could be temporary or permanent weakness to this region of the lip.

There is also risk of injury to the Hypoglossal Nerve. This is the nerve that the surgery is designed to stimulate. If injury was to occur, one side of the tongue could be weak, possibly causing a mild slurring of speech and limited success of the operation (reported up to 18% in the first 18 months).

Pneumothorax: Placement of the Breathing Sensor Lead necessitates dissection between the rib muscles immediately adjacent to the lung. If the covering of the lung, the pleura, was injured (rare) this could lead to a lung collapse which would need additional surgical intervention to repair.

Poor scarring: There will be 2 separate incisions performed for this surgery. If any heal poorly, then scar revision might be considered. Of note, you will see and feel the Generator under your skin in the right upper chest region.

Inadequate improvement to your OSAS: The vast majority of implanted patients are quite satisfied with the HNS improvements in OSAS and snoring. Data reports a 68-79% decrease in sleep apnea events and a 70% decrease in the blood oxygen desaturation events. Statistically about ¾ of the patients will find at least a 50% decrease in the AHI with the final AHI < 20.

Your operation will be carried out under a general anesthetic. As with any type of surgery, the risks of anesthesia such as drug reaction, breathing difficulties and even death are possible (fortunately exceedingly rare). Please feel free to discuss any specifics of the anesthesia with your anesthesiologist.

There are potential additional risks once the HNS is activated. These include discomfort from stimulation (reported up to 47% in the first 18 months), tongue abrasion (reported at 24% within the 1st 18 months), mouth dryness, discomfort from the physical presence of the device (reported at 8% within the 1st 18 months). Like any new electronic device there will also be a learning curve initially affecting usability or functionality of the device (reported at 11% within the 1st 18 months). 75%-93% of these additional risks were eventually resolved. About 3 months after implantation, you will undergo an in-lab sleep study to assess efficacy and further modify the implant settings if needed.

EXPECTATATIONS/LIMITATIONS:

Post-operative recovery: The surgery will be performed typically as an outpatient. Very limited activity for 2 weeks so to not to overuse your pectoralis muscle. If sutures are placed these will be removed in about a week. You may shower 24 hours following surgery, but no baths for 1 week. There are no dietary limitations. Some pain is to be expected, typically resolves by 7-14 days. It is typically not severe. Pain medication will be provided.

Battery: The battery in the Generator has an 11-year life, at which time would need replacement. This requires additional surgery.

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MRI Conditional status: The current HNS model implanted is MRI 'conditional'. This means you can undergo some types, but not all types of MRI. You will be limited to MRI of 1.5T in magnetic strength and limited to 30 minutes of scanning over a 90 minute period. You **can** undergo any other imaging studies, such a plain x-rays, CTs or ultrasounds.

Airport security: You will need to carry an implant identification card if needed for airport security as the implant may trigger some of the alarms.

At Suburban Ear, Nose & Throat Associates, we take great pride in helping you understand your plan of care. If, at any time during your care, you have any questions or concerns, please call us at (847) 259 -2530.

I have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of non-treatment, the procedures to be used, and the risks and hazards involved. The alternative to this particular surgery is to not have the procedure performed. I have sufficient information to give this informed consent. I understand every effort will be made to provide a positive outcome, but there are no guarantees.

Patient SIGNATURE: _____

Patient Name PRINTED: _____

Date: _____ Time: _____

Witness: _____ Date: _____