



About Obstructive Sleep Apnea & Inspire® Upper Airway Stimulation (UAS) Therapy

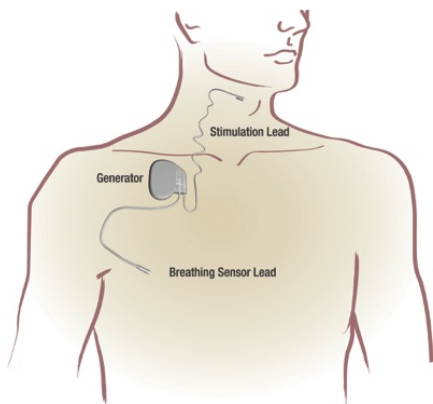
Obstructive Sleep Apnea

Eighteen million people each year are significantly impacted by the consequences of Obstructive Sleep Apnea (OSA). OSA occurs when the tongue and other soft tissues of the throat relax during sleep and obstruct the airway. This obstruction can happen at the soft palate, tongue base, or in many cases, both locations. When oxygen levels in the blood decrease, the brain senses a problem and arouses the body from sleep just long enough to open the airway. This cycle of obstruction and waking can repeat dozens of times per hour throughout the night, disrupting sleep. Daytime sleepiness, depression, weight gain, increases in automobile and industrial accidents, and a diminished quality of life are all commonly observed in people with OSA as a result of fragmented sleep patterns. Poorly managed OSA may lead to the development of systemic hypertension, cardiovascular diseases including heart failure and heart rhythm disorders, stroke and diabetes. The annual medical costs resulting from untreated OSA are estimated at \$3.4 billion.

CPAP, or Continuous Positive Airway Pressure, is the current standard of care for OSA. It is often successful when used correctly and regularly. CPAP requires patients to wear a mask while sleeping, and several studies have demonstrated that roughly half of all patients that start on CPAP therapy eventually become non-compliant. Other recommended treatments for OSA include lifestyle changes, weight loss, oral appliances and surgery. Most surgical options involve removing tissue and/or permanently altering a patient's anatomy, which can contribute to significant post-operative pain and long recovery times.

About Inspire Therapy

Inspire® Upper Airway Stimulation (UAS) is an FDA-approved treatment for people with moderate to severe OSA who are unable to use or get consistent benefit from CPAP. In contrast to CPAP, Inspire therapy works inside the body with a patient's natural breathing process. The implanted system includes a breathing sensor lead and a stimulation lead, powered by a small battery. An external handheld Inspire sleep remote is used to turn the therapy on before bed and off upon waking. When activated, Inspire therapy senses breathing patterns and delivers mild stimulation to key airway muscles, which keeps the airway open during sleep.



Inspire Therapy Advantages

In contrast to other surgical options to treat sleep apnea, Inspire therapy does not require removing or permanently altering an OSA patient's facial or airway anatomy. As such, the procedure is less invasive and may result in a shorter recovery time. It also does not require a mask or oral appliance. The Inspire system is usually implanted during an outpatient procedure, although in some cases patients may be kept overnight in the hospital for observation. One month after the device is activated, physicians optimize therapy settings for a patient during a routine sleep study. Patients typically return once a year for a checkup.

Clinical Evidence

The STAR (Stimulation Therapy for Apnea Reduction) trial was a clinical trial designed to evaluate the safety and effectiveness of Inspire therapy. It was conducted at 22 leading medical centers across the United States and Europe. Over a 12-month period, the trial closely monitored and evaluated 126 patients implanted with Inspire therapy. Enrolled patients had moderate to severe OSA, were unable to use CPAP therapy, had a body mass index of ≤ 32 , and passed a comprehensive airway anatomy examination.

Results were published in the January 9, 2014 edition of the *New England Journal of Medicine*. Patients who participated in the STAR trial experienced a reduction in apnea events and improvements along several indices designed to measure quality of life, including:

- 68 percent reduction in apnea hypopnea index (AHI)
- 70 percent reduction in oxygen desaturation events (ODI)
- Significant improvement in daytime functioning as measured by Epworth Sleepiness Scale (ESS) and Functional Outcomes of Sleep Questionnaire (FOSQ)
- 85 percent of bed partners reported no snoring or soft snoring for partners using Inspire therapy

Availability of Inspire Therapy

Inspire therapy is available at select U.S. medical centers across the United States. Patients can visit <http://www.inspiresleep.com/doctor-search/> to learn about availability in their area. New centers are always being added, so we encourage patients to check back often.

Inspire therapy is an evidence-based, FDA-approved therapy. The device costs approximately \$20,000 plus the cost of surgery, and is comparable to other neurostimulation devices currently available. Inspire therapy is being reviewed and approved by insurance companies on a case by case basis across the United States. Inspire-trained physicians work on their patient's behalf to gain insurance coverage. As of November 2015, 67 commercial insurers/Medicare Advantage programs have reimbursed for the cost of Inspire therapy. Additionally, Inspire therapy is on the Federal Supply Schedule, making it available for veterans, active military members, and beneficiaries.

To learn more, please visit www.inspiresleep.com, or call 1-844-OSA-HELP (1-844-672-4357).

About Inspire Medical Systems, Inc.

Inspire Medical Systems, Inc., based in Minneapolis, Minn., was formed in 2007 when the technology and a significant intellectual property portfolio was spun-out of Medtronic. Inspire Medical Systems has developed the world's first fully implanted neurostimulation device approved by the FDA for the treatment of Obstructive Sleep Apnea (OSA). Privately held, investors include Aperture Venture Partners, GDN Holdings, Johnson & Johnson, Kleiner Perkins Caufield & Byers, Medtronic, OrbiMed Advisors, Synergy Life Science Partners, TGap Ventures and US Venture Partners.



Inspire therapy was developed by Inspire Medical Systems, Inc. (Minneapolis, Minn.)

Safety information for Inspire therapy is provided at www.inspiresleep.com. Inspire therapy is not for everyone. Information at this site should not be used as a substitute for patients talking with their doctor. Patients are encouraged to review this safety information and talk with their doctor about diagnosis and treatment options.