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

Obstructive Sleep Apnea

Obstructive Sleep Apnea (OSA) affects approximately 18 million Americans. 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, leading to an unrested night of sleep. When left untreated, OSA can lead to devastating effects on heart and brain health, including increased risk for hypertension, stroke, and heart failure, impair quality of life, and increase both motor vehicle and occupational accident risk. 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. Although it is often successful when used correctly and regularly, studies show about half of people given a CPAP machine are unable to use or get consistent benefit from it. 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.

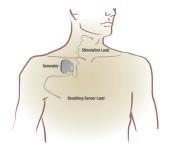
About Inspire Therapy

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. Based on these unique breathing patterns, the system delivers mild stimulation to key airway muscles. By stimulating these muscles, the airway remains open during sleep.

Inspire is implanted during a short, outpatient procedure. Most patients return home the same day, and can resume non-strenuous activities within a few days or as directed by their doctor.

The Inspire system consists of a breathing sensor lead and a stimulation lead, powered by a small battery. The therapy is controlled by a small handheld sleep remote. The remote allows the patient to turn the device on before bed and off when you wake up, increase and decrease stimulation strength, and pause during the night if needed.

One month after the device is implanted, the patient returns to the physician's office to activate the device. One month after activation, the physician optimizes the therapy settings for the patient during a routine sleep study. Patients typically return once a year for a checkup.







Inspire Therapy Advantages

In contrast to other surgical options to treat sleep apnea, Inspire therapy does not require removing or permanently altering a 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.

Clinical & Commercial 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. 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.

12-month STAR Trial results were published in the January 9, 2014 edition of the *New England Journal of Medicine*, and Inspire therapy received FDA approval in April 2014. 12-month results show patients receiving Inspire therapy experienced significant reductions in sleep apnea events and significant improvements in both quality of life and daytime functioning as measured by various questionnaires. There also was a high safety profile, with an overall rate of serious adverse events of <2%.

36-month study outcomes were published in November 2015, showing the improvements observed at one-year were sustained at the three-year follow-up mark.

As of January 2017, there are 28 peer-reviewed publication on the safety and efficacy of Inspire therapy. Please visit https://www.inspiresleep.com/for-healthcare-professionals/publications/ for more information.

Availability of Inspire Therapy

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

Insurance Coverage

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 February 2017, over 170 commercial insurers have reimbursed for the cost of Inspire therapy. Medicare is reimbursing for the cost of Inspire therapy based on medical necessity across most geographies. 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, Amzak Health, 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.