

What is OSA:

Obstructive Sleep Apnea (OSA) affects 22 million Americans. OSA occurs when soft tissues in the airway collapse during sleep and block the flow of oxygen to the brain. The brain senses a lack of oxygen and wakes the body up just long enough to take a breath, then the body falls back asleep. This cycle repeats throughout the night and causes poor, disruptive sleep. When left untreated, OSA can cause vehicle and workplace accidents, worsening mood and memory, stroke, heart attack, and even death.

Treatment Options:

There are many different sleep apnea treatment options available. Continuous Positive Airway Pressure (CPAP) is the most commonly used treatment for OSA. CPAP uses a mask and hose to blow pressurized air into the airway to keep it open during sleep. This treatment works well for some patients, however studies show about 50% of people who are given a CPAP machine don't use it. Other treatment options include oral appliances and major anatomy altering surgeries.

Inspire Therapy:

Inspire works inside the body with a patient's natural breathing process to treat sleep apnea. Inspire delivers mild stimulation to key airway muscles, allowing the airway to open during sleep. The patient uses a small handheld remote to turn Inspire on before bed and off when they wake up. No mask, no hose, just sleep.

The Inspire Procedure:

The Inspire system is made of a small battery and 2 small wires. Inspire is placed under the skin of the neck and chest through three small incisions during an outpatient procedure. Most patients return home the same day and return to non-strenuous activities within a few days. Over-the-counter pain medicine is typically used for a few days after the procedure for pain management.

Inspire Sleep Remote:

Inspire is controlled by the patient using the small, handheld Inspire Sleep Remote. The Inspire Sleep Remote is used to turn Inspire on before bed and off in the morning. Additionally, the patient can pause therapy during the night if needed and increase/decrease therapy settings.







Indications:

Inspire therapy was FDA-approved in 2014 and, as of October 2020, is used by over 10,000 people worldwide. Over 300 leading medical centers have been trained to offer Inspire as part of their sleep apnea treatment options.

Inspire is for people who:

- Have been diagnosed with moderate to severe Obstructive Sleep Apnea, specifically an Apnea-Hypopnea Index (i.e. the number of times they stop breathing each hour) between 15 and 65
- Are unable to use or get consistent benefit from CPAP
- · Are not significantly overweight
- Are over age 18

Clinical Results:

The safety and efficacy of Inspire was measured during the STAR clinical trial. One-year STAR trial results were published in January 9th, 2014 edition of the *New England Journal of Medicine*, showing patients using Inspire therapy had significant reductions in sleep apnea events and significant improvements in quality of life measures. These significant reductions and improvements were sustained over a 5-year follow-up period.

As of October 2020, there have been over 100 peer-reviewed publications on Inspire therapy. These publications show that patients using Inspire therapy in real world, clinical practice settings experience significant reductions in sleep apnea events and significant improvements in quality of life measures, consistent with those seen in the STAR clinical trial.

Notable outcomes of Inspire include:

90% of bed partners reported no snoring or soft snoring¹
79% reduction in sleep apnea events¹
94% of people are satisfied with Inspire²
96% of Inspire patients say Inspire is better than CPAP & would recommend Inspire to others²

- 1: Woodson et al., OTO-HNS 2018.
- 2: Heiser et al., ERJ 2019.