Inspire® Upper Airway Stimulation (UAS) Therapy

The first fully implanted, clinically proven obstructive sleep apnea therapy for patients unable to use CPAP

inspire®
UPPER AIRWAY STIMULATION

What Is Obstructive Sleep Apnea?

Obstructive sleep apnea, or OSA, is a condition that disrupts breathing during sleep. OSA occurs when the tongue and other soft tissues relax during sleep and obstruct the airway.

Without fresh air, the oxygen level in the blood decreases. The brain senses a problem and arouses the body from sleep just long enough to open the airway. Regular breathing is restored, but only for a few breaths, and then collapse occurs again—restarting the apnea cycle. This cycle of obstructions and waking can repeat dozens of times per hour throughout the night, disrupting sleep.

Common symptoms of OSA include snoring, daytime sleepiness, irritability, or difficulty with focus or concentration. If left untreated, OSA can lead to secondary health issues such as:

- Heart attack
- Heart failure
- High blood pressure
- Irregular heartbeats
- Stroke
- Weight gain

Current Treatment Options

Current treatment options for OSA range from lifestyle changes, to external device-based treatments, such as continuous positive airway pressure (CPAP), to surgery.

Lifestyle changes such as losing weight, exercising regularly, or consuming less alcohol before sleep may help improve sleep. If lifestyle changes alone do not resolve OSA, CPAP is typically prescribed.

CPAP is the most common treatment for OSA. CPAP is an effective treatment that uses a mask to deliver air pressure and keep the airway open. While CPAP is often successful, some people are unable to use or adhere to this treatment.

Oral appliances may be prescribed as an alternative to CPAP. Oral appliances keep the airway open by holding the jaw forward during sleep.

Surgical options may be considered by some people who are unable to use or adhere to CPAP or oral appliances. Traditional sleep apnea surgery is intended to make the airway larger by removing or altering facial or airway anatomy. These anatomy altering surgeries can be painful and involve lengthy recovery times.

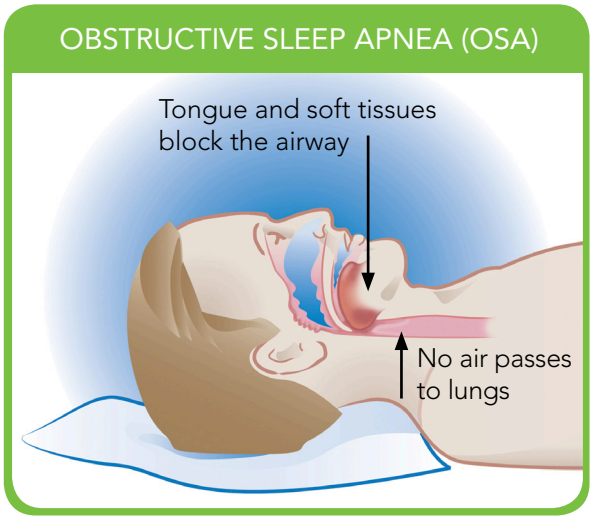
Now, there is a new FDA-approved option that uses stimulation therapy to keep the airway open during sleep.

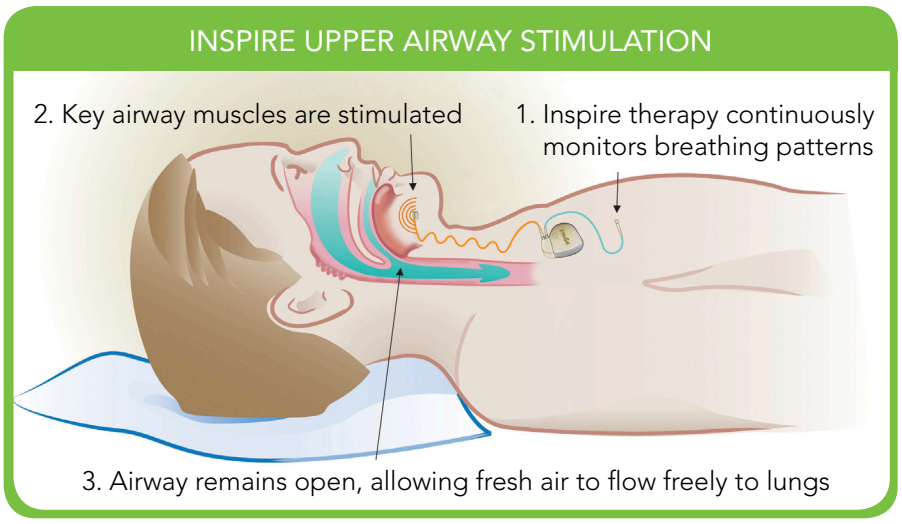
What Is Inspire Therapy?

Inspire therapy is a small, fully implanted system that senses breathing patterns and delivers mild stimulation to key airway muscles, which keeps the airway open during sleep. The system consists of three fully implanted components: a small generator, a breathing sensor lead, and a stimulation lead.

Using the small handheld Inspire sleep remote, a patient turns therapy on before bed and off upon awakening.

Inspire therapy is a truly unique approach to OSA that may be an option for people who are unable to use CPAP and do not want to consider traditional, anatomy altering surgery.





Becoming a Candidate

Clinic Visit

Inspire therapy represents a major advance in sleep apnea treatment for some patients who are unable to use CPAP. So, how do you determine if you are a candidate for Inspire therapy?

First, you will need to schedule a visit with your doctor. Your doctor will check your overall health and ask you some basic questions to determine if you meet the criteria for Inspire therapy.

People who may qualify for Inspire therapy

- Have been diagnosed with obstructive sleep apnea
- Have either failed or not tolerated CPAP treatment
- Have a body-mass index, or BMI, of 32 or less
- Do not have any other active implantable devices, such as a pacemaker
- Do not have certain diseases or conditions that may disqualify them as candidates

Sleep Study

If your doctor determines that you meet the basic criteria, you can proceed to a sleep assessment where your doctor will evaluate the severity and type of your sleep apnea. If your doctor determines that you have moderate to severe OSA (AHI between 20–65) and that less than 25% of your apneas are due to central sleep apnea, the next step is to have your airway anatomy assessed.

Airway Assessment

The first assessment is a basic evaluation of your airway anatomy that takes place in your doctor's office. For the second assessment, you will visit the hospital or surgery center to have a short procedure called a sleep endoscopy. Your doctor will examine your airway with an endoscope while you are under light sedation. This procedure helps identify the cause of your sleep apnea.

After these assessments, your doctor will determine if Inspire therapy is right for you.

Implant Procedure and Expectations

Implant Procedure

The implant procedure is performed in a surgery center or hospital under general anesthesia. Based on your recovery, you may be able to go home the same day you have the surgery, or your doctor may want you to stay in the hospital overnight.

You should expect some pain and swelling at the incision sites for a few days after the implant. However, within a few days following the procedure, you should be able to return to normal non-strenuous activities. You should avoid strenuous activities for about two weeks or as directed by your doctor.

A week after surgery, your doctor will examine you to make sure you are healing properly. Most patients have a full recovery within two weeks.

Therapy Activation

Three to four weeks after the Inspire system is implanted, you will have an appointment with your doctor to turn the system on for the first time and establish your personalized therapy settings. The goal for this appointment is for your doctor to determine stimulation settings that will be comfortable yet effective for you and for you to learn how to use the Inspire sleep remote.

Therapy Optimization

After you use the therapy at home for a few months, you will return to the sleep lab for an overnight sleep study where your therapy settings may be adjusted and optimized. Additional visits with your doctor may be needed to adjust therapy settings.

Routine Follow-ups

Following these final adjustments, general check-ups, including a physical exam and a routine device check, will occur 1–2 times a year.

Inspire Therapy Clinical Results

Inspire therapy has undergone significant clinical testing. After conducting three early studies to confirm basic safety and effectiveness, Inspire Medical Systems received approval in 2010 to begin a large clinical study called the STAR trial.

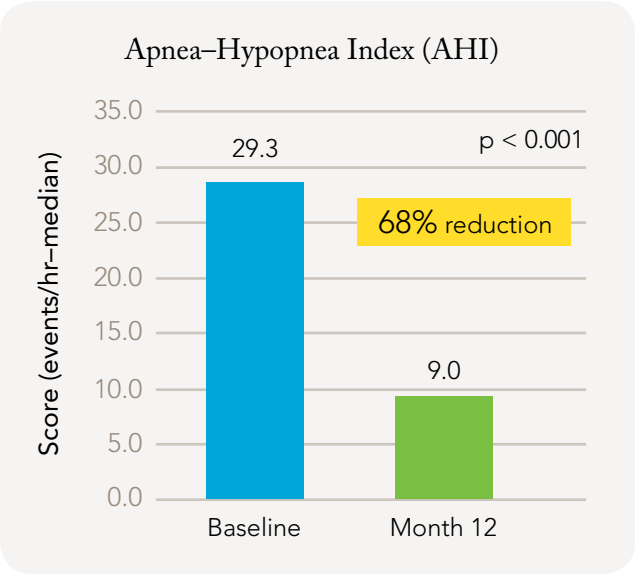
The STAR trial was conducted at 22 leading medical centers across the United States and Europe. During the STAR trial, 126 patients were implanted with Inspire therapy and closely monitored for over a year.

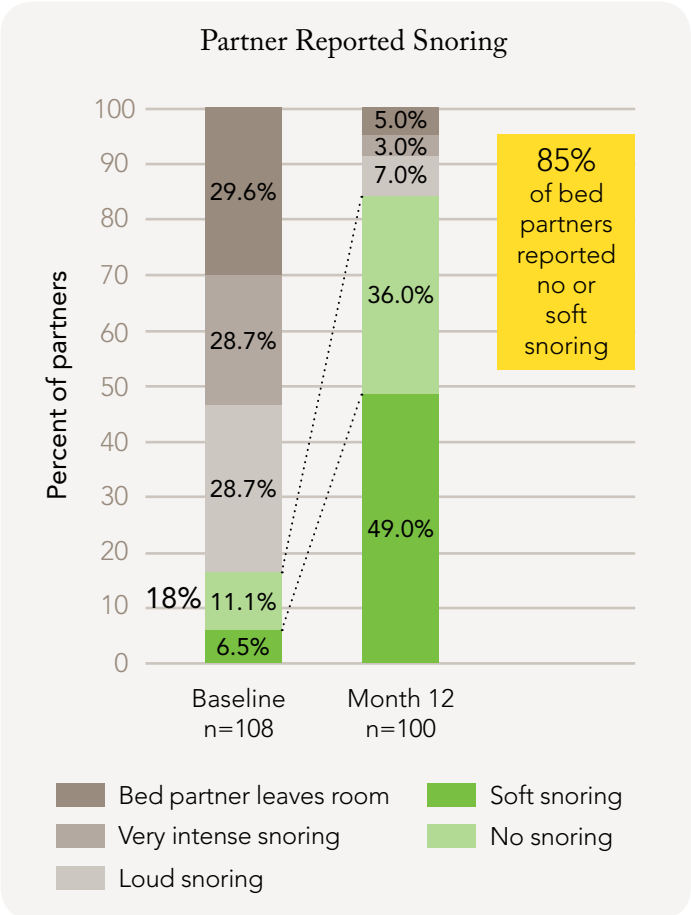
Patients implanted with Inspire therapy in the STAR trial experienced a 68% reduction in airway obstruction as measured by the apnea–hypopnea index, or AHI.

STAR trial participants also experienced significant improvements in quality of life and daytime functioning as measured by two validated instruments commonly used to assess quality of life in sleep apnea patients.

During the STAR trial, snoring was also assessed. In the STAR trial, 85% of bed partners reported either no snoring or soft snoring for their partners using Inspire therapy.

STAR trial results were published in the January 9, 2014 edition of the *New England Journal of Medicine*.





Frequently Asked Questions

What Does the Stimulation Feel Like?

You will likely feel a tingling sensation or mild contraction in your tongue muscles. The stimulation should not be painful or uncomfortable. The stimulation is programmed to deliver therapy without waking you from sleep.

Will Inspire Therapy Address Snoring?

Data from the STAR clinical trial showed that 85% of bed partners reported either no snoring or soft snoring for their partners using Inspire therapy. However, it is important to note that while Inspire therapy may improve snoring, it is not intended to treat snoring.

Will the Inspire System Limit My Activities?

Generally, no. However, you should ask your doctor about any activities that are particularly strenuous, (e.g., weight lifting) or that entail a large or unpredictable range of motion of your upper body and/or arms (e.g., working as a firefighter). Your doctor may ask you to refrain from certain activities or to approach them with precaution.

Are There Medical Imaging Technologies That Should Be Avoided?

You should not undergo an MRI once you have Inspire therapy implanted. The magnetic fields of MRI scanners may cause harm to components of your implanted system and may also cause tissue damage. Alternative imaging technologies such as CT, ultrasound, and others may be most suitable for you. Discuss your options with your doctor.

Can I Use a Microwave Oven and Common Household Appliances?

Yes, you may use a microwave oven and common household appliances as long as they do not emit strong magnetic fields.

If you have additional questions,
please visit www.InspireBetterSleep.com

What Risks or Safety Precautions Should Candidates Be Aware Of?

Inspire therapy is indicated for a subset of patients with moderate to severe OSA who are unable to use CPAP. As with any surgical procedure, there are risks and benefits associated with Inspire therapy. Risks include, but are not limited to, pain, nausea, temporary tongue weakness, and infection. Patients should discuss all potential risks and benefits of the therapy with their doctor. A full list of risks and benefits for Inspire therapy can be reviewed at www.InspireBetterSleep.com.

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