

Hypoglossal Nerve Stimulation (HNS) – Inspire®

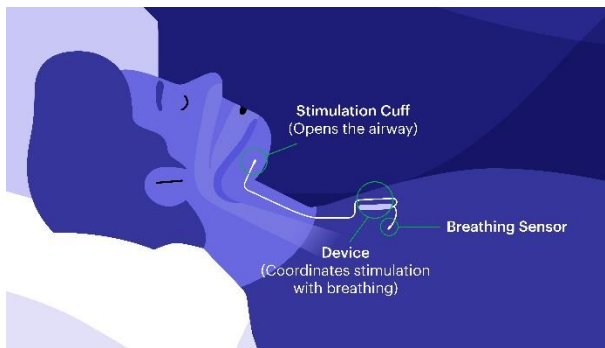
Getting treatment for obstructive sleep apnea is important because, if left untreated, it can lead to increased risk of stroke, heart attack, diabetes, memory loss, automobile accidents and other serious diseases.

There are several current options for treatment of obstructive sleep apnea (OSA). The goal of sleep apnea treatment is simple... Keep your airway open so that your breathing is not interrupted when you sleep.

Many people need treatment and the first and most common treatment for sleep apnea is CPAP, which stands for continuous positive airway pressure. CPAP uses a mask and hose to blow pressurized air into your airway. The force of the air keeps your airway from closing. CPAP works for a lot of people. But others just struggle to get consistent benefit.

Those who struggle with positive airway pressure devices (CPAP and BiPAP) may consider other treatments such as oral appliances, surgeries such as UPPP (uvulopalatopharyngoplasty) or MMA (maxillomandibular advancement) or Upper Airway Stimulation (UAS), a hybrid therapy that is surgically placed but adjustable like CPAP.

**Components of
Implanted System**



**Controlled by
Patient Remote**



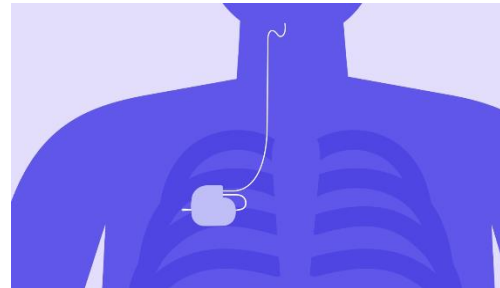
Inspire® Upper Airway Stimulation is a Federal Drug Administration (FDA) approved treatment that includes an implanted system, and a patient remote. Inspire is indicated for second-line treatment of moderate to severe Obstructive Sleep Apnea in adult patients with an apnea-hypopnea index (AHI) between 15 and 65. Inspire therapy is not intended for patients with a complete concentric collapse at the level of the soft palate, or those in whom central and mixed apneas make up 25% or more of their apnea-hypopnea index.

The Inspire Procedure

The system delivers mild stimulation to the hypoglossal nerve which controls the movement of the tongue and other key airway muscles. By stimulating these muscles, the airway remains open during sleep.

Inspire is inserted under the skin in an outpatient procedure that takes two to three hours. Most patients go home the same day.

The procedure consists of 2 incisions: 1 in the upper right chest where a small device is placed; and 1 just under your chin where the hypoglossal nerve is located.



Benefits

Inspire therapy has been demonstrated to significantly reduce the severity of obstructive sleep apnea (OSA). Proper treatment may lead to an increase in the ability to perform daily tasks and a decrease in risks associated with untreated OSA: accidents (e.g., motor vehicle accidents), hypertension, stroke, diabetes, vascular disease, heart failure, and early mortality.

Potential Health Risks

- Infection
- Tongue Weakness
- Swallowing or Speech Related
- Revision Intervention
- Discomfort
- Tongue Abrasion
- Insomnia/Arousal

Activities to Avoid:

Component manipulation: Do not manipulate (move) or rub your stimulator or leads through your skin. This could lead to dislodgement, damage to the components, skin damage or unintended stimulation.

Scuba diving or hyperbaric chambers: Do not dive below 30 meters (100 feet) of water or enter hyperbaric chambers above 4.0 atmospheres absolute.

Frequently Asked Questions:

Your doctor has suggested that you might benefit from having the Inspire® device implanted due to the fact that you do not tolerate or benefit from CPAP, BPAP or APAP therapy. It is important to understand what to expect after having the Inspire procedure to assist you in making this decision.

Here are answers to some of the most common questions.

How does Inspire therapy work?

Inspire works inside your body with your natural breathing process to treat obstructive sleep apnea. While you sleep, Inspire delivers mild stimulation to key airway muscles, allowing the airway to remain open. The Inspire system is controlled by a small handheld sleep remote. You turn Inspire on before bed and off in the morning when you wake up.

What does the stimulation feel like?

You should feel a mild sensation from the stimulation when the therapy is turned on. Typically, patients feel a tingling sensation or mild contraction in their tongue muscles. Then stimulation is delayed for a period of time while you fall asleep. After this start delay, stimulation resumes. The stimulation is gentle and designed to move the tongue forward without disturbing your sleep.

Will I be able to increase or decrease the strength of stimulation?

Yes. A range of stimulation will be programmed by your doctor, and the Inspire sleep remote allows you to adjust the strength of stimulation.

The stimulation should not be painful or uncomfortable. Stimulation strength can be adjusted so that therapy is comfortable and effective.



How long is the recovery time after surgery?

You should expect some pain and swelling at the incision sites for a few days after the implant. Based on your recovery, you may be able to go home the same day you have the surgery, or your doctor may want to keep you overnight.

Within a few days following the procedure, you should be able to return to normal nonstrenuous 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.

Will the Inspire system limit my activities?

Generally, no. However, you should ask your doctor about any activities that are particularly strenuous (e.g., weightlifting) or that entail a large or unpredictable range of motion of your upper body and/or arms (e.g., working as a firefighter).



Can the device be removed?

It is possible to safely remove Inspire through a surgical procedure when medically necessary. However, this is rare and not recommended in most situations.

Will I need additional sleep studies?

You will need at least one sleep study so your doctor can fine tune your therapy settings. Your doctor may need additional sleep studies to monitor and adjust your therapy settings.

Can I go through airport security with Inspire?

It is safe to go through security screening devices with Inspire. It is possible that Inspire would set off the metal detector so you should let security personnel know that you have an implanted stimulator and carry your Inspire Identification Card for verification.

| Inspire | | | |
|--|-----------|------------|----------------------|
| Name: John Doe | | | |
| Address: 123 Any Street | | | |
| City: Verylong Cityname | | | State or Country: MN |
| Phone: 123-456-7890 | | | |
| Please contact Inspire if your personal information changes. | | | |
| PRODUCT | MODEL NO. | SERIAL NO. | IMPLANT DATE |
| PIG | 3024 | | 00/00 |
| Stimulation Lead | 4063 | | 00/00 |
| Sensing Lead | 4323 | | 00/00 |
| Medical Device Identification | | | |

How long does the Inspire battery last?

The battery in Inspire is designed to last for approximately 11 years. Once it is running low, it is replaced during a short outpatient procedure.

What are the steps after the procedure?

The first 4 to 6 weeks after the procedure the system remains off to allow you to heal. You'll then have an appointment to have the system programmed with initial settings, receive the remote for your device and learn how to use it.

You will then begin using Inspire every night, slowly increasing the amplitude until you reach the point where you are having comfortable restful sleep.

After you've gotten used to using the device at home for about 12 weeks, you will have an overnight sleep study. At that time, the technician will observe your sleeping and fine-tune the device to the best possible way to treat your sleep apnea.

What will the incisions look like after I have healed from the procedure?

The visibility of the scars will depend on your skin tone and individual healing process. To the right, you can see examples from three patients.

