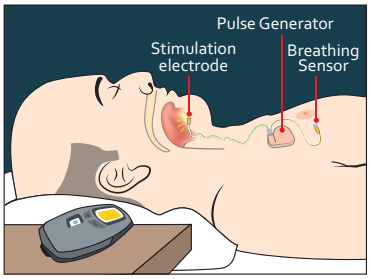
Upper Airway Stimulation/Hypoglossal Nerve Stimulator

An alternative treatment for Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) is a common sleep disorder and if not treated, can lead to many health problems. Continuous positive airway pressure (CPAP) is the standard first line treatment for OSA, but some people may not be able to use CPAP or get good benefit from it. If you are unable to use CPAP, there are other forms of treatment you may want to try. These include various oral appliance devices, upper airway surgery, or upper airway stimulation (UAS). This fact sheet describes the UAS device and how it works. For more information on OSA, CPAP, and other treatment options, see the ATS Patient Information Series at www.thoracic.org/patients.



What is upper airway stimulation (UAS)?

With OSA, the muscles and soft tissue in the throat area and the tongue relax during sleep, causing collapse of the upper airway and blockage of airflow. The Inspire® Upper Airway Stimulation (UAS) device (also called Hypoglossal nerve stimulation or HNS device) is a surgical option for OSA. The UAS device is implanted in the chest and works to stimulate the tongue to keep the upper airway open during sleep. An upper airway stimulation device sends an electrical signal to the hypoglossal nerve, which is a nerve that goes to the tongue. When the nerve is stimulated, it gently nudges the tongue to move forward and prevents the tongue from blocking the air passage.

What are the advantages of UAS therapy?

Some advantages of UAS are:

- it may be an easier treatment to tolerate for people who can't stand wearing a CPAP mask
- there is no extra equipment to clean and maintain
- there are no ongoing supply costs
- when you travel you only need to carry a small remote

Who is a candidate for Upper Airway Stimulation?

1. Adults who are older than 18 years of age and have a body mass index (BMI) *less than* 32kg/m² (see the resource listing on how to calculate your BMI).
2. People with moderate or severe OSA. This is based on the results of a sleep study (polysomnogram) showing an apnea-hypopnea index (AHI) of 15-65 events per hour.
3. People who are unable to tolerate positive airway pressure (PAP) therapy for OSA.

You are not a candidate to try the UAS device if you are very obese or have central sleep apnea. If you do meet the above criteria and are interested in this therapy, you should discuss this with your healthcare provider. Your healthcare provider can refer you to a sleep specialist or an Ear, Nose and Throat (ENT) surgeon who can advise you if this is the best therapy for you.

You will need to have a test called a drug-induced sleep endoscopy (DISE) to see if you are eligible for a UAS device. You will be given a medication to make you sleepy. While you are asleep, the surgeon or sleep provider will look into your upper airway with a small camera. The specialist will look at your tongue and throat structures during sleep to see if you may benefit from placement of the UAS device.

How does the device work?

There are four components to the UAS device (see figure):

1. A generator that is surgically implanted in the chest just below the collar bone
2. A breathing sensor electrode that is surgically implanted on the side of the chest by the ribs
3. A stimulation electrode that is surgically implanted around the hypoglossal nerve of the tongue
4. A small remote control used to control (turn on and off) the device

Each time you make an effort to breathe, the breathing sensor detects your breathing effort and sends a signal to the generator. The generator then signals the stimulation electrode to act on the nerve that causes your tongue muscles to contract. With every stimulation, your tongue is gently moved forward to keep your airway open. You can adjust the setting for level of stimulation based on how it is working.

The device is controlled using a small remote control. You turn on the device during bedtime and turn it off when you wake up. You can also pause the device when you wake up in the middle of your sleep.

What to expect during UAS surgery

Surgery to place a UAS device is typically an outpatient procedure that is done under general anesthesia. Three small incisions are made on the skin. The small battery-operated generator is implanted on the chest under the skin and soft tissue below the collar bone. The breathing sensor electrode is placed under the rib cage. The stimulation electrode is wrapped around the hypoglossal nerve that is located under the jaw. The surgery is

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generally well tolerated with minimal risk of complications. You go home the same day after you recover from the anesthesia.

What are possible complications of the surgery?

Like any surgery, you can get infection and bleeding at the surgical site. You should expect some pain after the surgery, but this is generally mild, and well tolerated when treated with oral pain medications. The pain should get better within a couple of weeks. Nerve injury is a rare complication which occurs in less than 1 in 100 people. This is usually temporary but can lead to abnormal tongue movement. It almost always gets better on its own in about 6-8 weeks.

When can I start using the UAS device after surgery?

UAS is not used right after surgery. The surgical scars are allowed to heal for about a month or two prior to turning on the device for the first time. A longer healing time may be needed for some people. Your healthcare provider will determine the best timing for your device to be turned on. When your provider turns on the device for the first time (usually during an outpatient clinic appointment), you should not expect any pain. Your healthcare provider will guide you through the process and will adjust the settings on your device depending on your tongue movement and comfort. You will learn how to operate your remote control so you can adjust the settings of your device. You will be given a range of settings that you can adjust at home. The settings will range from a low number to a high number. The higher the number, the stronger the signal to the nerve.

What should I expect after my device is turned on?

Once your healthcare provider turns on your device, you should be able to start using the device at home. For the next 3 months, the goal is for you to get used to the device. You should use the device every night for the entire time that you are asleep. Using your remote control, you will need to slowly increase your setting (which is the strength of the signal from the generator to the nerve) based on your healthcare provider's instruction. If you are having issues tolerating it, contact your healthcare provider.

Once you are used to the device, you will need to have a sleep study to check how well the UAS is working to treat your OSA. During the study, the setting on the device can be adjusted to find the best settings that will treat your sleep apnea. You will be told if any change in your settings is needed based on the results of your sleep study.

You will need to follow closely with your healthcare provider to ensure that the therapy is working well for you. At each clinic visit, your healthcare provider will check the settings and battery level of your device and how many hours you are using the device. Adjustments can be made to your settings based on your comfort and symptoms.

How do I care for my implant?

Once the surgical wounds have healed, there are no particular precautions necessary. You should always have reserve batteries for the remote. The battery in the generator will last for about 10 years. At that point, it will need to be replaced during an outpatient surgery. You should contact your healthcare provider if you have any issues or concerns.

Can I go through security at airports?

You should have no problem at the airport while going through the security scanner. You should let the TSA (Transportation Security Administration) officer that you have stimulator (pacemaker type device) implanted to avoid any inconvenience. You will receive a device identification card to carry with you stating that you have a surgically implanted device.

Can I get x-rays, CT scans or MRI scans with UAS?

For medical purposes, you should have no issues getting CT scans or X-rays of any parts of your body. Whether you can get MRI scans depends upon the model of the device and the technique of the MRI. You should always notify any healthcare provider about your device when planning such testing. You should always carry the device identification card as that will make it easier to explain what you have to medical staff and providers. More details about MRI scans are available on https://www.inspiresleep.com/for-healthcare-professionals/mri-information/

Reference: Upper Airway Stimulation for Obstructive Sleep Apnea. Strollo et al. NEJM 2014; 370:139-49

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Rx *Action Steps*

- ✔ Speak with your healthcare provider if you are having issues with PAP therapy or think that you are not getting the benefit as expected with PAP therapy.
- ✔ Ask about other therapies for sleep apnea that you may be able to try.
- ✔ Ask about upper airway stimulation device and discuss whether this is an option for you.
- ✔ Always practice good sleep habits and exercise regularly.

Healthcare Provider's Contact Number:

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Resources

American Thoracic Society

- www.thoracic.org/patients/
  - Obstructive Sleep apnea
  - CPAP therapy for OSA
  - Sleep Studies
  - Alternative Therapies for OSA
  - Healthy Sleep in Adults

BMI calculator

- https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

American Sleep Apnea Association

- https://www.sleepapnea.org/treat/sleep-apnea-treatment-options/

Inspire Medical Systems

- http://manuals.inspiresleep.com/
- https://www.inspiresleep.com/for-healthcare-professionals/our-technology/