

# NEWSLETTER

## Upper airway stimulation promising treatment for sleep apnoea

ELECTRICAL STIMULATION of the hypoglossal nerve is proving to be a promising treatment for moderate to severe obstructive sleep apnoea (OSA) in patients who do not respond to or can't tolerate continuous positive airway pressure (CPAP) therapy.

OSA affects an estimated 5% to 10% of people in the United Kingdom and is undiagnosed in most of them.

Until very recently, the only treatments with any real track record were throat surgery and a sleep machine with a face mask that many compared to Darth Vader's.

Many patients have tried the continuous positive airway pressure (or CPAP) machine but find they can't stand it, reporting that it was noisy, made them claustrophobic, and the hose that the mask connects to bothered them every time they tried to move. "I could not get over it," is a common response.

The CPAP has been the standard of care for sleep apnoea for three decades, and it helps nearly all the people who faithfully use it — although negative reaction is quite common. Many patients who say they use their CPAP don't use it enough to keep them safe, sleep clinics are reporting.

Things may be about to change dramatically, however. For example, Inspire Medical Systems, based in Minneapolis, is awaiting approval from the U.S. Food and Drug Administration for its Upper Airway

Stimulation system, which uses a pacemaker-like device to stimulate a branch of the hypoglossal nerve controlling the tongue muscles, thus preventing the tongue from slipping back during sleep and blocking the airway.

There are also other innovative systems being developed, and these include:

American company Airing LLC is promoting a disposable micro-CPAP device that weighs less than an ounce, fits in the nose, and has no cords or hoses.

Its design includes battery powered "micro-blower" technology that blows the amount of air pressure prescribed by the patient's physician into the airway to effectively treat OSA.

The Winx Sleep Therapy System by ApniCure Inc. of Redwood City, California, is a small mouthpiece that rests inside the sleeper's mouth, creating suction to open the throat.

An alternative on the low-tech end for people with mild to moderate apnea, adjustable dental appliances help keep the lower jaw up and forward, opening the airway.

Approval for the use of any new therapy in the United Kingdom will only be given after rigorous testing by medical experts, and it may be some time before they become available.

# Disposable micro-CPAP weighs less than an ounce

AMERICAN ENTREPRENEUR Stephen Marsh — who currently has more than 75 patents to his name—is the founder behind Airing LLC, a company that next month will seek funding for what it says is a disposable micro-CPAP device that weighs less than an ounce, fits in the nose, and has no cords or hoses.

Airing says the device will address pervasive concerns about obstructive sleep apnoea patients' CPAP noncompliance.

Airing's design includes battery powered "micro-blower" technology that blows the amount of air pressure prescribed by the patient's physician into the airway to effectively treat OSA.

While conducting research in another field, Marsh saw the applicability and need for a new CPAP solution due to a personal connection with the dangers of breathing disorders.

Marsh then shared his design and concept with medical professionals and knowledgeable medical experts in the area of breathing disorders, all of whom fully endorsed his approach and proposed solution.

"I think it's going to be wonderful for people. For the first time we have a treatment that patients will be willing to use. I think Airing will have a tremendous impact," says Jeffrey Bass, MD, of Brigham & Women's Hospital and a member of Airing's medical advisory board.

The solution is the result of Marsh's research in the area of micro-fluidic pumps in the micro electro mechanical systems space, which identified a host of inefficiencies and limitations with current solutions and led to Marsh's design for a better micro-fluidic pump design, a design that works just as well moving air.

The "micro-blowers" solution in Airing benefits from advances in the "Roll to Roll" manufacturing process, which allows for inexpensive mass manufacturing of the solution, and which will allow Airing devices to be low-cost and disposable.

"As someone with a family member who suffers from sleep apnoea (my brother), I understand the potential serious health impacts of this condition," Marsh says.

"As a result of recent research, I realised that current pumps possess several deficiencies which severely limit their effectiveness and saw an opportunity to apply a new design to these pumps that could be used in a variety of ways, including treating breathing disorders. The result is a solution that

we believe has the potential to address this area, and to help a large number of people live better, healthier lives."

Airing plans to launch on crowdfunding this month.



# How upper airway stimulation works

## Product name: Inspire® Upper Airway Stimulation (UAS)

**What is it?** The Inspire Upper Airway Stimulation (UAS) system is an implantable nerve stimulator used to treat moderate to severe obstructive sleep apnoea (OSA). The Inspire UAS system consists of implanted components including the implantable pulse generator (IPG), stimulation lead, and sensing lead and external components including the physician programmer and the patient programmer (sleep remote).

**How does it work?** The IPG detects the patient's breathing pattern and maintains an open airway with mild stimulation of the hypoglossal nerve, which controls tongue movement, during inhaled breathing. The physician adjusts the stimulation settings using the external physician programmer. The patient sleep remote allows the patient to turn therapy on before they go to sleep and to turn therapy off when they wake up

**When is it used?** The Inspire UAS system is used to treat a subset of patients with moderate to severe OSA (apnea-hypopnea index [AHI] of greater or equal to 20 and less than or equal to 65). The system is used in adult patients 22 years and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse (as seen during drug induced sleep endoscopy) at the soft palate level.

PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as:

- 1 Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or
- 2 Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).

**What will it accomplish?** One hundred twenty-six (126) patients took part in a clinical study in 22 different sites. The Inspire UAS

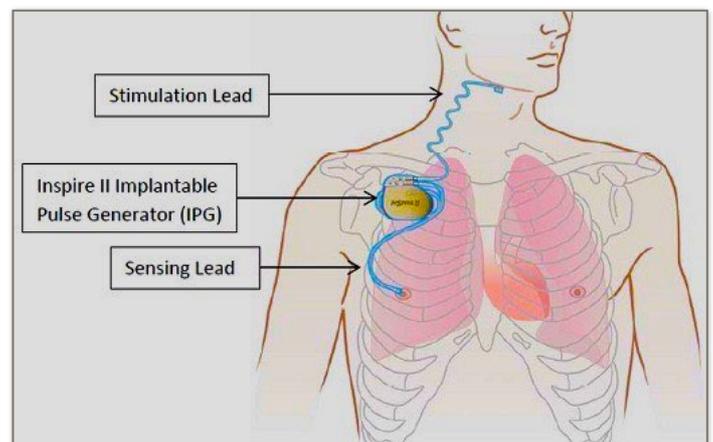
therapy provided the majority of patients with significant reductions in the severity of their obstructive sleep apnea and improvements in their quality of life.

More than half of all patients experienced at least a 50% reduction in AHI and an AHI of less than 20 events per hour at the end of the 12 month study. Patients also experienced at least a 25% reduction in oxygen desaturation index.

**When should it not be used?** The system is contraindicated for:

- Central + mixed apneas greater than 25% of the total AHI.
- Any anatomical finding that would affect the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate.
- Any condition or procedure that would affect neurological control of the upper airway.
  - Patients who are unable or do not have the necessary assistance to operate the sleep remote.
  - Patients who are pregnant or plan to become pregnant.
  - Patients who will require magnetic resonance imaging (MRI).
  - Patients with an implantable device that may have unintended interactions with the Inspire system.

Additional information: The Summary of Safety and Effectiveness Data and labelling are available online.



# Snoring, Tossing or Turning?

OVER THE years, many people have expressed dissatisfaction with their sleep patterns. Often people say they do not feel they get enough sleep at night, and they wake up in the morning not feeling refreshed.

Pharmaceutical companies know that there are millions of people who do not sleep well throughout the night. As a result, there are a myriad of medications on the market that are being prescribed by medical professionals as well as being sold over the counter in supermarkets, pharmacies, etc...

Medical professionals say that 8 hours of sleep per night is ideal for adults. Statistics show that 15% of adults between the ages of 19 to 64 report that they get less than six hours of sleep during weekday nights.

An estimated 43% of Americans between the ages of 13 to 64 report that they seldom or never get good sleep during the week, and approximately 60% of individuals state that they are suffering from sleep deprivation every night.

The most common complaints are snoring, waking up intermittently, and feeling tired in the morning.

Researchers say that the human body experiences two levels of sleep, which are NREM (non-rapid eye movement) and REM (rapid eye movement).

Our sleep cycles begin with NREM, which occurs when we first fall asleep, REM begins about 90 minutes after the NREM cycle and subsequently recurs about every 90 minutes. NREM occupies about 75% of the night starting with light sleep, which is between sleep and wakefulness.

This is followed by the onset of sleep in which we become unaware of our surroundings. At this stage, the breathing and heart rate become regulated, and the body temperature is lowered. In the third and fourth stages, breathing slows down, muscles become relaxed, tissue grows and repairs, energy is replenished, and hormones are released.

During the REM cycle, which occurs 25% of the night, the body becomes immobile, the eyes dart back and forth, dreaming occurs, and the brain and body are recharged.

So, the question is – How does sleep deprivation affect the human body?

The following are symptoms of not getting enough sleep during the night:

Nodding off during the day which accounts for 100,000 car accidents annually in the U.S.A.

Lowered cognitive functioning, which affects memory retention and increases the occurrence of heart disease, diabetes, and strokes.

Diminished sex drive, which is caused by lack of sleep that lowers the testosterone levels in males.

Premature ageing of the skin, which is caused by the flooding of cortisol (stress hormone) in the body.

As a result, cortisol breaks down collagen in the skin.

Weight gain, which increases the risk of becoming obese by 30%.

Increased rate of depression. A study in 2007 showed that people who experienced insomnia were five times more likely to develop depression.

Here are some helpful tips, which can significantly improve your sleep pattern:

Establish and adhere to a regular bedtime regimen.

Get up at the same time every day, which includes days off.

Take a short 30-minute nap during the day, if you did not sleep well the night before.

Try to avoid sleeping in past your normal wake-up time. Stay active in the evening in order to avoid going to sleep too early.

Make sure the room is dark before going to sleep. Light sources coming from the TV, computer, smartphone, or tablet can reduce the production of melatonin in the body.

Avoid drinking caffeinated beverages, alcohol, and nicotine during the latter part of the day.



# Seven reasons to avoid surgical procedure

FOR MANY of you, the idea of sleeping with a mask or something inside your mouth makes you cringe, writes Dr Steven Park, M.D. Sleep apnoea is taking a toll on your personal and professional life, and you're willing to consider surgery. You do your research, but find that there are so many different opinions about sleep apnoea surgery, it's impossible to make any sense in deciding on the options.

For a summary of how to decide if surgery is right for you, read my report, "The Truth About Sleep Apnoea Surgery."

In this post, I will reveal seven reasons why you should avoid sleep apnea surgery. In my next post, I'll go over seven good reasons to think about surgery for sleep apnoea.

## 1. You're severely overweight

Studies have shown that the more overweight you are, the less likely any surgery for sleep apnoea will succeed. In general losing significant weight will lower your sleep apnoea severity by only one level (severe to moderate, moderate to mid, etc.). However, once you do lose a lot of weight, you can be a better candidate for surgery.

One type of surgery that I recommend often is nasal surgery. In general, it's not going to cure you of your sleep apnoea. However, being able to breathe better through your nose can make CPAP or dental appliances (or even future surgery) work much better.

## 2. You have severe OSA

In general, the more overweight you are, the less likely you'll respond to sleep apnoea surgery. If you can lose a significant amount of weight, then the better your chances for surgical success.

## 3. Your surgeon recommended a UPPP only

There are exceptions to this situation, but in general, a uvulopalatopharyngoplasty (UPPP) along has less than a 40% chance of surgical success. "Let's do the UPPP to see if it works" is not a good answer. Your surgeon should make recommendations based on the published data, personal experience and your unique situation.

## 4. Many hospitals and surgeon are not experienced with OSA surgery

Most ENT surgeons will be familiar with basic sleep apnea procedures, but there are very few that do a variety of different surgical procedures at different levels of the throat. Since undergoing anaesthesia with sleep apnoea also places you at a higher risk, it's important that the anaesthesiologist and hospital is well experienced in treating patients with obstructive sleep apnea.

## 5. You haven't tried CPAP or dental devices

From a practical standpoint, it's unlikely that your insurance company will approve any kind of surgery if you have not tried a CPAP or dental appliance first. Medically speaking, it's generally recommended trying non-surgical options before considering surgery.

## 6. Your nose is stuffy

The more stuffy your nose is, the less likely throat surgery will help. This concept applies to CPAP and dental appliances, and it applies to surgery as well.

## 7. You don't have family or friend's support

Undergoing any type of surgery is a big commitment. You'll need help making errands, doing chores around the house and to help you cook and eat meals. Most importantly, it's vital that your family members are supportive of your decision.



# Link between sleep apnoea and depression in men

NEW RESEARCH presented at the 2015 American Thoracic Society International Conference in Denver, Colorado, reports a link between sleep disorders and depression in men.

The study found excessive daytime sleepiness and severe obstructive sleep apnea were individually associated with the prevalence and onset of depression ~ with the combination of both associated with even greater risk.

Previous research has observed an association between sleep apnoea and **depression**. For instance, a 2012 study published in the journal *Sleep* claimed to be the first nationally representative survey ~ taking in 9,714 American adults ~ to examine this relationship. That study found sleep apnoea symptoms were associated with probable major depression, regardless of weight, age, sex or race.

In the new study, researchers from the University of Adelaide in Australia studied 1,875 male participants between the ages of 35 and 83 over a period of 5 years.

The study found that excessive daytime sleepiness and severe obstructive sleep apnoea (OSA) were individually associated with the prevalence and onset of depression ~

with the combination of both associated with even greater risk.

OSA is estimated to affect 1 in 2 men and 1 in 5 women, but up to 82% of cases are undiagnosed, according to the researchers.

Men with an undiagnosed sleep disorder and excessive daytime sleepiness ~ which is a primary symptom of sleep apnea ~ were found to be four times more likely to have depression than peers who did not have a sleep disorder. Men with a diagnosed sleep condition, meanwhile, were found to be twice as likely as peers without a sleep disorder to have depression.

Dr. Carol Lang, postdoctoral research fellow in the University of Adelaide's Department of Medicine, says the link between sleep disorders and depression is very strong. She encourages clinicians to examine male patients reporting symptoms of depression for symptoms of sleep disorder and vice versa.

They hypothesised, however, that CPAP "might ameliorate the symptoms by improving sleep continuity, by ameliorating the adverse effects of various neurotransmitters, [or] by alleviating the adverse effects of any attendant hypoxemia." Importantly, the improvement in depression symptoms appeared to be sustained and long term.

## NOTE TO READERS:

*Would you like to receive your future newsletters by email? If so, please send your email address to [kathy@wideopenspace.co.uk](mailto:kathy@wideopenspace.co.uk) and instead of a postal copy it will arrive on your computer as soon as it is published. Thank you.*

**Chairman - Mike Wilson**

Tel: 01381 621660

email:

[mike.wilson.2000@gmail.com](mailto:mike.wilson.2000@gmail.com)

**Secretary - Mrs. Lesley Bagnall**

Tel: 07513 198543

email: [taysidesasa@gmail.com](mailto:taysidesasa@gmail.com)

**Treasurer - Scott Elliot**

Tel: 01450 375046

email:

[scottelliot659@btinternet.com](mailto:scottelliot659@btinternet.com)

## S.A.S.A CONTACTS

**Membership Secretary -**

**Helen Rowson**

Tel: 07742 440688

email:

[membershipsasa@gmail.com](mailto:membershipsasa@gmail.com)

**Minutes Secretary - Tom Irvine**

Tel: 01294 214236

email: [tomirvine@f2s.com](mailto:tomirvine@f2s.com)

**Newsletter Editor -**

**Murray Phillips**

Tel: 07786 955564

email:

[murrayjphillips@gmail.com](mailto:murrayjphillips@gmail.com)

**Website Administrator ~**

**Kathy Curran**

Tel. 07796564609

email:

[kathy@wideopenspace.co.uk](mailto:kathy@wideopenspace.co.uk)