Inspire® Upper Airway Stimulation System for obstructive sleep apnoea

TECHNOLOGY

The Inspire® Upper Airway Stimulation System by Inspire Medical Systems is an implanted device intended to treat moderate to severe obstructive sleep apnoea (OSA).

The device stimulates the hypoglossal nerve, which in turn stimulates the muscles of the base of the tongue and upper airways with the aim of preventing the base of the tongue covering and obstructing the airways during sleep.

The closed-loop pulse generator (implanted under the skin near the collar bone) creates the impulses that implanted leads carry to the hypoglossal nerve. A respiration sensor helps to synchronise the stimulation with the patient’s breathing. A clinician initially programmes the settings of the device using a programming console. Then day-to-day control passes to the patient.

The device is aimed at patients who have found current, non-invasive treatments to be inadequate and who have a significant amount of obstruction of the airways caused by the base of the tongue. OSA has been reported to affect four percent of middle-aged men and two percent of middle-aged women in the UK. Only one in four of these people will be diagnosed and only one in eight will have access to treatment. No information was found for this alert on the number of patients for whom the base of the tongue is the most significant form of obstruction.

Hypoglossal nerve stimulation is not currently available in the UK for any patient group. The device was CE marked in December 2010 and it is estimated that the device will become commercially available in the UK in Q3 2013.

An assessment of hypoglossal nerve stimulation for OSA was published by the Health Policy Advisory Committee on Technology (HealthPACT) in Australia in August 2012.

SIMILAR TECHNOLOGIES IN DEVELOPMENT

Two similar devices in development are the Apnex Hypoglossal Nerve Stimulation (HGNS®) System and the Aura6000™ Targeted Hypoglossal Neurostimulation (THN) Sleep Therapy.

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POTENTIAL FOR IMPACT

Many patients with OSA respond to non-invasive treatment with continuous positive airway pressure (CPAP). If shown to be effective, hypoglossal nerve stimulation may therefore provide a new treatment option for those with moderate-to-severe obstructive sleep apnoea for whom current non-invasive treatments are ineffective and who are considering surgical options. This seems to be the first time neurostimulation has been commercially available in the UK to treat OSA.

The company states that this technology treats the root cause of OSA in some patients (those in whom the base of the tongue obstructs the airway while asleep). They also comment that this approach is completely reversible and less invasive than currently available surgical options. They expect that patients may be hospitalised for less time than they currently are for surgery although in some patients, existing surgical options may also still be needed to address sources of airway obstruction other than the base of the tongue.

The company anticipate that using this technology will be an additional cost to the NHS and will require training of staff and some service reorganisation. However, they expect that this will be balanced by a reduction in OSA symptoms and improvements in patients’ quality of life. They state that this may lead to a reduction in the overall cost of treating OSA and its associated conditions.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


ONGOING STUDIES


INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.