Nyxoah Genio™ System for obstructive sleep apnoea

TIMEFRAME: Estimated earliest commercial availability in the UK

TECHNOLOGY

Nyxoah Genio™ System developed by Nyxoah S.A. is an implantable neurostimulation device for people with moderate to severe obstructive sleep apnoea (OSA). The Nyxoah Genio™ System stimulates the hypoglossal nerve, triggering the tongue to contract and maintain an open upper airway.

The Nyxoah Genio™ System consists of three components: 1) an implantable stimulation device 2) an activation chip and disposable patch and 3) a charging unit.

The tiny neurostimulator is implanted under the chin using a minimally invasive procedure. The stimulator’s electrodes are placed in contact with both branches of the hypoglossal nerve. The activation chip connected to a disposable patch is positioned every night by the patient on the skin under the chin. The activation chip has its own battery and wirelessly activates the implanted neurostimulator. After each night of use, the disposable patch is removed and the activation chip is plugged into the charging unit until fully charged.

Nyxoah Genio™ System is intended to be used as second line therapy for people with moderate to severe OSA who are not compliant or have refused continuous positive airway pressure (CPAP) therapy.

Nyxoah Genio™ system is expected to be CE marked and launched into the UK NHS in the next 18 months.

POTENTIAL FOR IMPACT

Obstructive sleep apnoea (OSA) is the most common sleep disorder and is a condition in which a person experiences repeated episodes of obstructed airflow (apnoea) because of a narrowing or closure of the pharyngeal airway during sleep. This is usually caused by a
decrease in the tone of the muscles supporting the airway, which either completely or partially obstructs the airway and decreases airflow (hypopnoea). People with OSA can experience several apnoea and hypopnoea episodes per night and have disturbed sleep as they experience micro arousals to restore normal breathing. The degree of severity is measured by the Apnoea Hypopnoea Index (5-14 mild, 15-30 moderate, 30+ severe).

The symptoms of OSA include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, morning headaches and sexual dysfunction. Many people with OSA develop high blood pressure, which if left untreated can increase the risk of other cardiovascular diseases and stroke.

Treatment of OSA aims to reduce daytime sleepiness by reducing the number of episodes of apnoea and hypopnoea experienced during sleep. Initial management is with lifestyle advice and support to lose excess weight, stop smoking, limit alcohol consumption and avoid the use of sedatives. CPAP is recommended as a treatment option for adult with moderate or severe symptomatic OSA. Alternative treatment options include mandibular advancement devices, surgery to open up the airway, and soft palate implants if indicated.

The company claim that the key advantage of the Nyxoah Genio™ system is its minimally invasive and short implantation procedure. The dissociation of the implantable stimulator from its power unit, may improve comfort and ease of use. It is also more discreet compared to current treatment options such as CPAP, which may improve compliance. Nyxoah Genio™ implant is not battery operated so further surgical procedures to remove and replace it are not required. The system is also MRI compatible and the company claim that another advantage is its bilateral nerve stimulation, which is expected to allow for a more efficient therapy compared to existing treatment methods.

This technology is predicted to have an impact on the following domains of the NHS Outcomes Framework (https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017)

Domain 2 Enhancing quality of life for people with long-term conditions;

EVIDENCE

COMPLETED UNPUBLISHED STUDIES


ONGOING STUDIES


INFORMATION FROM

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

The Nyxoah Genio™ system is a device to treat people with obstructive sleep apnoea (OSA) who are not suitable for continuous positive airway pressure (CPAP) therapy. OSA is a common sleep disorder where the walls of the throat relax and narrow during sleep, interrupting normal breathing. The Nyxoah Genio™ system consists of a device which is implanted under the chin, and a disposable patch with an activation chip which is worn on the chin every night. The patch wirelessly stimulates the nerves of the tongue to make it contract and prevent obstruction of the airway. The activation chip is removed every morning and recharged. The developer says the advantage of the device is that it can be easily implanted, that it is discreet and could improve quality of life and compliance for people with OSA.