The remedē® System for central sleep apnoea

Technology ALERT
Horizon Scanning Centre
August 2013

TECHNOLOGY

The remedē® System is an implantable device in development by Respicardia, Inc. which is designed to restore a more normal breathing pattern during sleep in people with central sleep apnoea.

The implanted part of the system includes a pulse generator connected to a stimulation lead and, optionally, to a sensing lead. A surgeon implants the pulse generator under the skin below the collarbone. The attached stimulation lead is placed within veins which lie close to a branch of the phrenic nerve, which serves the diaphragm. If required, the sensing lead is placed within the azygos vein.

The stimulation lead (which lies in either the right brachiocephalic vein or left pericardiophrenic vein) delivers electrical pulses to the phrenic nerve – a technique also known as transvenous phrenic nerve stimulation. The stimulation of the phrenic nerve is unilateral (one-sided) and intended to regulate breathing by controlling the diaphragm. The sensing lead detects breathing and sends this information back to the pulse generator.

The system also includes an external programmer which a doctor can use to adjust the pulse generator settings and to review diagnostic data.

Clinical trials of the remedē® System have so far been primarily in people with heart failure and atrial fibrillation with co-existing central sleep apnoea.

The remedē® System received a CE mark in August 2010. The estimated date for commercial availability in the UK was not known for this Alert.
POTENTIAL FOR IMPACT

The company suggest key innovative features of the remedē® System are that it is fully implantable, automatically provides therapy while a patient sleeps, and unilaterally stimulates the phrenic nerve to allow people to breath during sleep in the same manner as when they are awake. They also state that, as the system is automated, it has no patient compliance issues in contrast to current therapies which require the patient to wear a mask during sleep.

Potential benefits to patients who have the system may include decreased mortality and improved ejection fraction, heart failure symptoms and sleep. There may also be benefits for the health services in terms of a reduced number of hospitalisations and prescriptions for sleep medications.

If the remedē® System is proven to be clinically effective and given a place in the treatment of central sleep apnoea, there would be costs to the health system in terms of the cost of the system itself and the surgery to implant it. Staff training to implant and programme the device and to follow up the patient would also be required.

EVIDENCE

PUBLISHED PAPERS


COMPLETE UNPUBLISHED STUDIES

ONGOING STUDIES

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