Health Technology Review	
Technology Ref.:	HTA23058
Technology Name:	NeuRx DPS® Diaphragm Pacing System
Approvals by International Bodies:	**PMA FDA approves diaphragm pacing system from Synapse Biomedical for patients on ventilators.**
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Short Description of the Technology:	The NeuRx Diaphragm Pacing System (NeuRx DPS®) is an intramuscular, percutaneous, motor point diaphragm stimulation system. It is comprised of an External component External Pulse Generator , EPG) and implantable Electrodes (Permaloc Electrodes). The device electrodes are implanted using standard laparoscopic surgical techniques and are connected to a four-channel external pulse generator at a percutaneous exit site. The pulse generator controls the pulse delivered through clinician programmed parameters of pulse amplitude, pulse duration, pulse frequency, pulse ramp, inspiration time, and respiratory rate. The user connects the device and turns it on for use; no other controls are available or necessary for operation. Diaphragm Pacing is used to replace, delay and reduce use of invasive mechanical ventilation in indicated patients. It is used to recondition the diaphragm muscles through applying electrical impulses that are transmitted to the diaphragm through intramuscular implanted electrodes. The electrodes are implanted through a minimally invasive abdominal laparoscopic surgery

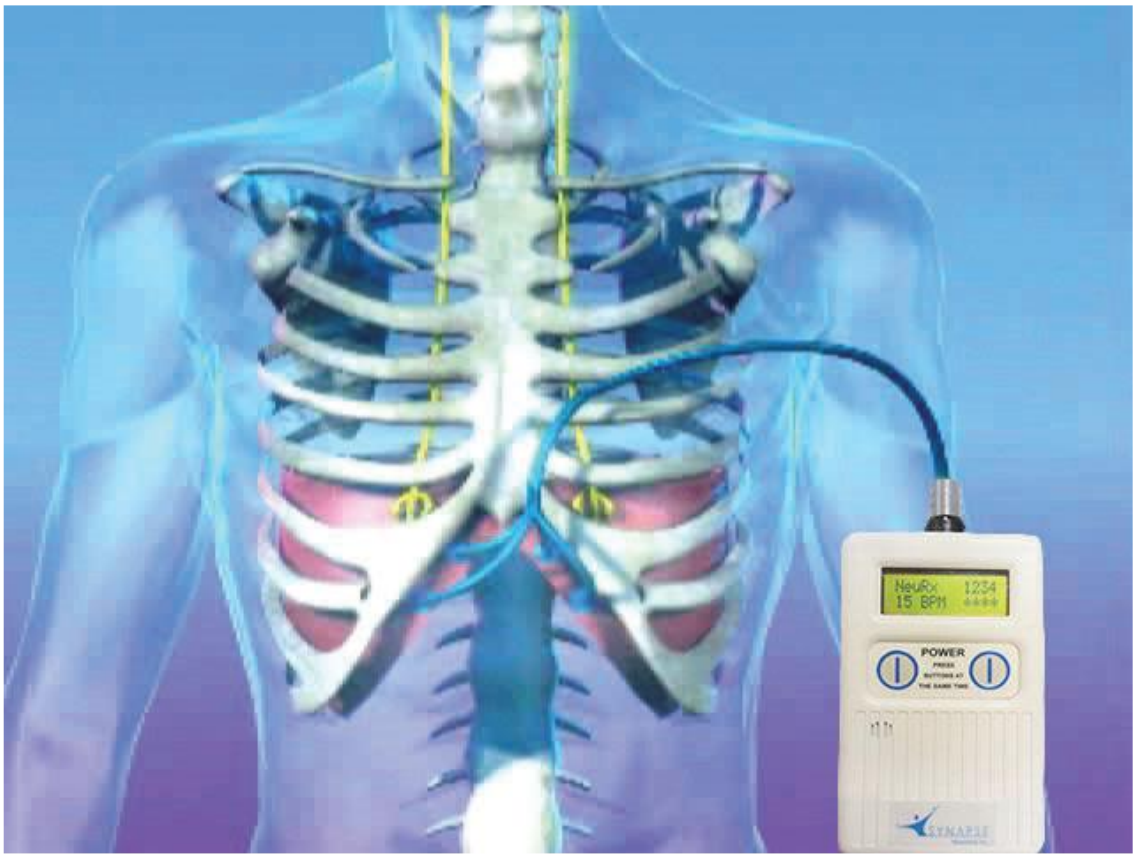
Health Technology Assessment Team Recommendation:	**Approve with limitation**
Summary of Review:	
The NeuRx Diaphragm Pacing System (DPS) uses electrical impulses to stimulate the diaphragm muscles of people with high spinal cord injuries who can no longer breathe on their own. It is used to strengthen the diaphragm muscles after they haven't been used in a long time and then act as a breathing pacemaker to stimulate those muscles and allow for breathing without the help of a mechanical ventilator. The main components of the system include: four implanted electrodes, a clinical station for programming, an external pulse generator, and a patient controller. NeuRx DPS provides negative pressure ventilation. This mimics the body's natural breath cycle. The battery-powered device delivers electrical stimulation via four percutaneous intramuscular electrodes. These are implanted into the diaphragm through minimally invasive laparoscopy. The device is indicated to allow the patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours a day. DP is licensed for patients with spinal cord injury in several territories including the USA and Europe	

Advantages	Disadvantages
FDA approved technology for SCI patients with mechanical ventilator dependency	Diaphragm pacing is contraindicated for patients in whom the phrenic nerve is not functional
Helps improve respiratory mechanics (specifically spontaneous tidal volume)	The technology required a skilled surgeon & rehabilitation team (comprehensive critical care program)
Based on the available studies ; the technology Reduce and, in some cases, eliminate their dependency on mechanical ventilators Regain their independence by enhancing their mobility and transportation options Allowing them to sleep more comfortably and soundly without constant ventilator noise May allow for natural breathing through the nose and mouth rather than primarily through tracheostomy tube.	Potential complications include but are not limited to intraoperative damage to the phrenic nerve, vascular injuries, acute lung injury, pericardial and oesophageal injuries, diaphragmatic perforation, viscous perforation, and peritonitis.
Helps in Strengthening the diaphragm muscles after they haven't been used in a long time and then act as a breathing pacemaker to stimulate those muscles and allow for breathing without the help of a mechanical ventilator.	One reported adverse event recorded in 2022 and safety recall notices

We recommend an **approval with limitation of using this technology** with the following conditions:

1. Approval on the use of NeuRx DPS System; version 20-0030 limited to the following criteria:
   - Only for patients +18 with stable, high spinal cord injuries with stimulable diaphragms.
   - In specialized healthcare facilities with acute care units for spinal cord injuries and specialized rehabilitation centres with traumatic spinal Cord Injury (SCI) well defined care program.
   - In the presence of well-trained nurse and skilled rehabilitation team during the activation of the device.
2. For cost effectiveness and coverage of the technology, the request needs to be submitted by the provider for reimbursement through empanelment process.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image


Population, setting and intended user for Technology "NeuRx DPS® Diaphragm Pacing System"

- **Population/ Intended User**;
  - This device is intended for use in patients with stable, high spinal cord injuries with stimulable diaphragms, but who lack control of their diaphragms.
  - The NeuRx Diaphragm Pacing System is intended for use in patients 18 years and older with stable high spinal cord injuries who lack control of the diaphragm but who will benefit from diaphragm stimulation to help them breathe without relying on a mechanical ventilator. The system can support patient breathing continuously for 4 or more hours each day.
- **To be performed by**:
  - By skilled surgeon, monitored by well-trained nurse and in the care of skilled rehabilitation team.
- **Clinical Setting:**
  - Hospitals, special surgery centers.
- **Condition of use:**
  - The NeuRx DPS should not be used for patients with diaphragms that cannot be stimulated.
  - The NeuRx® RA/4 is contraindicated in patients whom the physician determines are not candidates for surgical procedures due to physical or mental conditions.
- **Exclusion criteria:**

  This device should be kept out of the reach of children. Safety has not been established for pregnancy, patients under the age of 18, patients with suspected or real heart problems, or patients who have implanted electrical devices or epilepsy. The long-term effects of electrical stimulation of the diaphragm are unknown. This device is electrically powered and may produce tissue damage or electrical hazard if improperly used. The system may be affected by excessive moisture, severe mechanical shock, diathermy, electro cauterization, and radiation therapy. Implanted patients should not be connected to high-frequency surgical equipment or subjected to magnetic resonance imaging (MRI). Care should be taken to avoid operation of this device in close proximity to shortwave or microwave therapy equipment. Discontinue use of this device if skin in the implant area becomes swollen, infected, or inflamed or if there are skin eruptions such as phlebitis, thrombophlebitis, or varicose veins. Adverse events related to the system include capnothorax, equipment failure leading to loss of breathing, infection, airway compromise, spasms, pain or discomfort with stimulation, and difficulty eating. Patients must have a mechanical ventilator available at all times.