PHAGENESIS®

Pharyngeal Electrical Stimulation System

with Phagenyx®

ICD-10-PCS Coordination & Maintenance Committee Meeting

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March 9, 2021

Agenda

- Disease Background
- Current Standard of Care Practices
- Phagenyx® Pharyngeal Electrical Stimulation System Overview
- Safety
- Regulatory Timeline
- Conclusion

Neurogenic Dysphagia

Disease Background

Normal Swallowing

- Swallowing is a complex sensorimotor process involving numerous precisely timed events that rely on interactions both in the central and peripheral nervous systems

What is Neurogenic Dysphagia?

- Swallowing difficulty due to disruption of neurological systems involved in safe swallowing
- Caused by broad range of underlying diseases (stroke, traumatic brain injury), care management interventions (prolonged mechanical ventilation), or a combination

Incidence

- >1.5 million adult patients in the US

Risks and Complications

- malnutrition, dehydration, weight loss
- reduced quality of life
- aspiration pneumonia
- increased re-hospitalization
- increased burden of care with longer length of stay
- increased mortality risk

Dysphagia Standard of Care

Current practices address the symptoms of dysphagia

Current Dysphagia Care Practices

- Risk Management:
  - Diet modifications
  - Compensatory Strategies
  - Postural Techniques
- Muscle Rehabilitation:
  - Swallowing exercises
  - Maneuvers
  - Muscle stimulation
  - Biofeedback
- Sensory Techniques:
  - Thermal-tactile-taste

Limitations of Current Practices

- Low quality evidence overall
- Reviews / meta-analyses do not show significant treatment effects
- Limited evidence for dose optimization and treatment standardization
- Most treatments require significant patient input and compliance and weeks of intensive therapy
- Unsuitable for early treatment

Phagenyx® PES System

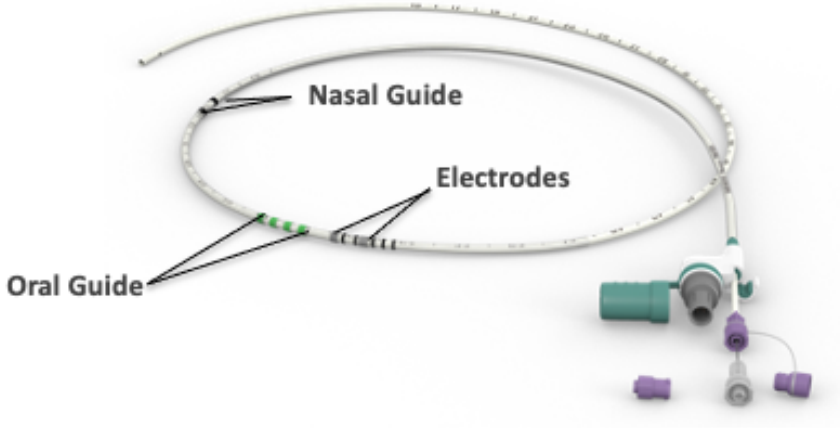
Designed to treat the underlying cause of neurogenic dysphagia

Phagenyx® Base Station

- Reusable across multiple patients
- Simple intuitive touch screen interface
- Low energy, high impact stimulation (5Hz)
- Optimized stimulation levels (1-50mA)
- Treatment and electrode monitoring
- Treatment and patient data storage

PNX-1000 Catheter*

- Sterile single patient use; one catheter per patient
- Catheter remains in place for whole treatment regimen
- Two parts – core NG tube and sleeve/electrodes
- Two functions – feeding and stimulation
- Targeted electrode placement (pharynx)
- Removed after treatment completion or enteral feeds



*ICD-10-PCS procedure code request is for single use catheter only

Phagenyx® PES

Mechanism of Action & Indications for Use

What does Phagenyx® do?

- Phagenyx® delivers electrical pulses to stimulate sensory nerve fibers (IX and X) within the pharynx
- Sensory nerve fibers signal the motor cortex in the brain, increasing cortical activity
- This promotes neuroplasticity and restores swallowing control through cortical reorganization
- Additionally, PES results in beneficially increased levels of neurotransmitters in the pharyngeal mucosa (Substance P) linked to improvements in swallow performance and protective cough reflex

Indications for Use

- The Phagenyx® System is intended for the treatment of non-progressive neurogenic dysphagia in adult patients
- Non-progressive neurogenic dysphagia is defined as all neurogenic dysphagia excluding that arising solely as a result of a progressive neurodegenerative disease or condition.
- Examples of non-progressive neurogenic dysphagia include but are not limited to; dysphagia due to brain injury (following stroke, traumatic brain injury, infection or inflammation), and dysphagia arising from prolonged mechanical ventilation and/or Critical Illness Polyneuropathy (CIP).

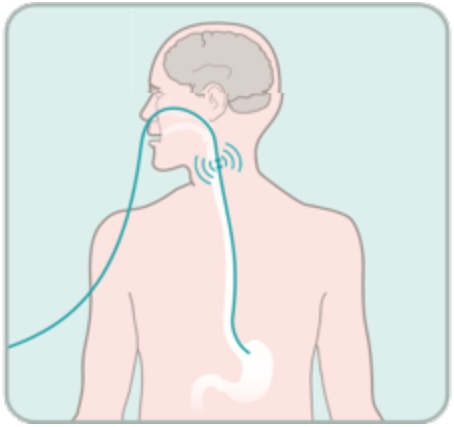
How is Phagenyx® used?

- Phagenyx® is used within an inpatient hospital setting as early as practical after the initiating medical event
- PES is delivered by a Phagenyx® trained and certified healthcare provider
- Delivery of PES via Phagenyx® System is documented within patient's daily treatment and/or progress notes
- Phagenyx® is a standalone treatment requiring modest patient involvement

Phagenyx® Procedural Steps

Catheter placed by healthcare professional trained and experienced in NG tube insertion

1. Nose-Ear-Xiphisternum (NEX) measurement and sleeve adjustment to fit patient's anatomy
2. Nasal insertion of catheter; positioning confirmed by integrated nasal guide (NEX)
3. Confirmation of stomach placement
4. Catheter is secured and guidewire removed
5. Connection to enteral feeding, if required



Stimulated by Phagenyx® trained and certified healthcare professional only

1. Electrode position confirmed by integrated oral guide
2. Connect catheter to Base Station
3. Threshold Level (lowest detection level)
4. Tolerance Level (highest level tolerated)
5. Stimulation Level tested and adjusted, if needed
6. Optimized stimulation delivered for 10-minutes
7. PES delivered once per day three consecutive days or up to six days, if needed

Catheter removed by healthcare professional trained and experienced in NG tube removal

1. Catheter removed following PES cycle or after continued use as an NG tube (up to 2-weeks)

Safety

Adverse Events and Associated Complications

Safety

- 25 years of clinical data in humans – consistent improvements in clinical outcomes
- No serious device or procedure related adverse events
- No evidence of any treatment related trauma at any stimulation level
- FDA agreement to categorize device and treatment as Non-Significant Risk

Potential Side Effects

- Infrequent side effects associated with Phagenyx® treatment to date, typically single occurrences
  - Temporary jaw chattering or atypical facial/ear pain if the electrodes improperly positioned
  - Temporary redness in the area of the electrodes
  - Transitory hypersalivation while being stimulated
  - Nausea during insertion of the catheter, consistent with NG tube insertion
  - Potential risk of tissue irritation over time which may lead to development of pressure sores, consistent with other indwelling catheters

Regulatory Timeline

2012

CE Mark Granted

- EU launch of Phagenyx®

2015

Phagenyx® confirmed as Class II device

2019

Breakthrough Device Designation

- FDA confirmed breakthrough device designation for treatment of ***neurogenic dysphagia in adult tracheotomized patients weaned from mechanical ventilation***

2020

Broad Use Claim Confirmed

- FDA confirmed broad use-claim for ***non-progressive neurogenic dysphagia***

2021

FDA De Novo Application Submitted

- FDA approval anticipated Q2 2021

Breakthrough Device Designation Expanded

- FDA expanded breakthrough designation to ***non-progressive neurogenic dysphagia***

Conclusion

- Dysphagia leads to poor outcomes, reduced quality of life, and increased mortality
- No FDA approved evidence-based interventions for treating the neurological component of non-progressive neurogenic dysphagia
- Phagenyx® is the first device to apply electrical stimulation to the pharynx for restoration of neurological function and physiologic swallowing control
- Phagenyx® can be readily integrated into the existing suite of treatments used in dysphagia care, as already shown in Europe

Questions?

PHAGENESIS