FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the of the Lungpacer Diaphragm Pacing Therapy System During the COVID-19 Pandemic

May 5, 2020

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Lungpacer Diaphragm Pacing Therapy System during the COVID-19 pandemic.

All patients who are treated with the Lungpacer Diaphragm Pacing Therapy System will receive the Fact Sheet for Patients: Emergency Use of the Lungpacer Diaphragm Pacing Therapy System During the COVID-19 Pandemic

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of Diaphragmatic Pacing Stimulator Systems?

- Devices that meet certain criteria for safety, performance, and labeling have been authorized for emergency use.
- The Lungpacer Diaphragm Pacing Therapy System is authorized for use in healthcare settings to assist in weaning patients on invasive mechanical ventilation who have been determined by their healthcare provider to be at high risk of weaning failure during the COVID-19 pandemic.
- Treatment is for a maximum of 30 days.
- Healthcare providers should review the Lungpacer Diaphragm Pacing Therapy System Instructions for use, the LIVE Catheter Kit Instructions for Use, the Intermediate Cable Instructions for Use, and the Handheld Controller Instructions for Use, including cleaning instructions, patient monitoring recommendations, and other labeling information for the Lungpacer Diaphragm Pacing Therapy System.

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

Who should be receiving this medical device?

Patients with COVID-19 and other illnesses or conditions who require invasive mechanical ventilation, and are at high risk of weaning failure.

What are the known and potential benefits and risks of the Lungpacer Diaphragm Pacing Therapy System?

Potential benefits of the Lungpacer Diaphragm Pacing Therapy System:

- Maintenance or improvement of diaphragm muscle strength to promote early weaning from mechanical ventilation
- Avoidance of risks of prolonged mechanical ventilation such as ventilator associated pneumonia (VAP), ventilator associated lung injury (VALI), muscle wasting, laryngotracheal injury, and death

Potential risks of the Lungpacer Diaphragm Pacing Therapy System:

- Infection, device breakage or migration into the heart, heart rhythm disturbance, bleeding, and, rarely, procedure-related death

- Risks associated with central venous catheters inserted via the subclavian vein including pneumothorax, hemothorax
- Risks of electrical stimulation of the phrenic nerve and diaphragm
- Reduced familiarity of healthcare providers with the Lungpacer Diaphragm Pacing Therapy System
- Lack of effectiveness after up to 30 days of treatment, despite use as intended

What are the alternatives to the Lungpacer Diaphragm Pacing Therapy System and the known and potential benefits and risk of such products?

Alternatives to the Lungpacer Diaphragm Pacing Therapy System that is authorized under this Emergency Use Authorization (EUA) include "traditional" weaning strategies based on manipulation of ventilator settings modes which allow or encourage gradually increased patient effort and stamina for breathing.

Benefits associated with "traditional" weaning strategies:

- Non-invasive
- Healthcare provider familiarity with standard ventilator weaning strategies, including those described in clinical guidelines

Risks associated with "traditional" weaning strategies:

- Prolonged mechanical ventilation with associated risk, such as ventilator associated pneumonia (VAP), ventilator associated lung injury (VALI), muscle wasting, laryngotracheal injury, and death

What is an EUA?

The United States (U.S.) FDA has made the Lungpacer Diaphragm Pacing Therapy System available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

The Lungpacer Diaphragm Pacing Therapy System made available under an EUA has not undergone the full validation of an FDA-approved or cleared device. However, in the absence of an FDA-approved or cleared alternative and based on the totality of scientific evidence, it is reasonable to believe the Lungpacer Diaphragm Pacing Therapy System may be effective in assisting weaning of patients off ventilators and, as a result, may increase the availability of ventilators for other patients. The EUA for these devices are in effect for the duration of the COVID-19 pandemic, unless terminated or revoked (after which the device may no longer be used).

An FDA approved or cleared device should be used instead of the Lungpacer Diaphragm Pacing Therapy System under EUA, when applicable and available.

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**