

FACT SHEET FOR PATIENTS

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

May 5, 2020

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your healthcare provider believes that it is necessary to provide you with treatment using the Lungpacer Diaphragm Pacing Therapy System. This device may be effective in helping to get you off of the ventilator (also known as “weaning” you off of the ventilator).

This Fact Sheet contains information to help you understand the risks and benefits of using this device for treatment of patients during the COVID-19 pandemic. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

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- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**
 - <https://www.cdc.gov/COVID19>

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19, but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What do I need to know about the emergency use of the Lungpacer Diaphragm Pacing Therapy System?

The Lungpacer Diaphragm Pacing Therapy System has been authorized under an Emergency Use Authorization (EUA) for emergency use 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, in healthcare settings during the COVID-19 pandemic. Treatment is for a maximum of 30 days.

A healthcare provider may choose to treat you with this device if you are placed on a ventilator, in an effort to wean you off of the ventilator.

What is the Lungpacer Diaphragm Pacing Therapy System?

The Lungpacer Diaphragm Pacing Therapy System is designed to stimulate the diaphragm muscle, one of your breathing muscles, in order to improve your breathing muscle strength. This, in turn, may reduce the amount of time needed to get you off of the ventilator. The Lungpacer Diaphragm Pacing Therapy System may be used on patients during the COVID-19 pandemic who need to be placed on invasive ventilation and have a high risk of weaning failure. This device may allow patients to wean off of the ventilator in order to meet emergency demands for ventilators, critical care beds, and ICU personnel.

What is an EUA?

The United States FDA has made certain devices available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Services' (HHS's) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The Lungpacer Diaphragm Pacing Therapy System., made available under an EUA, has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, including when there are no adequate, approved,

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available alternatives, and when based on the totality of scientific evidence available, it is reasonable to believe that a diaphragm pacing system meets certain criteria for safety, performance, and labeling may be effective in treatment of patients during the COVID-19 pandemic.

The EUA for the Lungpacer Diaphragm Pacing Therapy System is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

What are the known and potential risks and benefits 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 the ventilator
- Avoidance of risks of being on the ventilator for a prolonged time, including pneumonia, lung injury, damage to your airway, and death

Potential risks of the Lungpacer Diaphragm Pacing Therapy System:

- Infection, breakage of the device, lung injury, pain due to stimulation, interference with your heart rhythm, bleeding, and, rarely, procedure related death
- Risks seen for patients who have central venous catheters (tubes inserted into a large vein)
- Risks of electrical stimulation of the phrenic nerve and diaphragm
- Reduced familiarity of some healthcare providers with new devices such as 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 are authorized under this Emergency Use Authorization (EUA) are “traditional” methods of weaning which include adjustment of the ventilator settings to allow you to gradually participate more in the work of breathing and to build up your stamina for breathing.

Benefits associated with “traditional” weaning methods:

- They do not involve an invasive procedure on your body
- Your healthcare provider will likely have more familiarity and experience with traditional weaning methods which are often described in clinical guidelines

Risks associated with “traditional” weaning methods:

- Risks associated with being on the ventilator for a prolonged time, including pneumonia, lung injury, damage to your airway, and death

Is the Lungpacer Diaphragm Pacing Therapy System FDA-approved or cleared?

No. The Lungpacer Diaphragm Pacing Therapy System is not yet approved or cleared by the United States (U.S.) FDA. An FDA approved or cleared device should be used, when applicable and available. Instead, FDA has made this device available under an emergency access mechanism called an Emergency Use Authorization (EUA). This EUA is supported by the

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Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of medical devices during the COVID-19 pandemic. This EUA for the Lungpacer Diaphragm Pacing Therapy System will remain in effect for the duration of the COVID-19 pandemic, unless it is terminated or revoked by HHS or FDA (after which the Lungpacer Diaphragm Pacing Therapy System may no longer be used).

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