

FACT SHEET FOR PATIENTS

Emergency Use of the VentFree Respiratory Muscle Stimulator During the COVID-19 Pandemic

May 1, 2020

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your healthcare provider believes that you may benefit from the VentFree Respiratory Muscle Stimulator (hereafter referred to as “VentFree”) while you are on a ventilator. The VentFree device may help reduce wasting of abdominal wall muscles that can occur while you are on a ventilator, and may thereby assist in getting you off of the ventilator (also known as “weaning off the ventilator”).

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

- **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 that one may show if infected with the virus. The virus most likely spreads from one person to another when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is VentFree?

VentFree is intended to be used by healthcare professionals in a healthcare facility to treat adult patients by reducing atrophy of the abdominal wall muscles while you are on the ventilator, which may reduce the number of days of ventilator support in patients who require mechanical ventilation. VentFree may be used on patients during the COVID-19 pandemic who need to be placed on a ventilator. This device may assist patients in weaning off of the ventilator in order to

meet emergency demands for ventilators, critical care beds, and ICU personnel.

What do I need to know about the emergency use of VentFree?

VentFree has been authorized under an Emergency Use Authorization (EUA) for emergency use in healthcare settings for treatment of patients during the COVID-19 pandemic by their healthcare provider to assist in successful weaning off of mechanical ventilation, for no more than 6 weeks.

A healthcare provider may choose to treat you with this device in an attempt to reduce your number of days on mechanical ventilation, and to reduce wasting of your abdominal muscles. VentFree is recommended until successful weaning or for no more than 6 weeks, whichever comes first.

What is an EUA?

The EUA is supported by the Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic. The particular use of the VentFree made available under this 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, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that VentFree may reduce atrophy of the abdominal wall muscles, which may reduce the number of days of ventilator support in adults who require mechanical ventilation in healthcare settings during the COVID-19 pandemic.

The EUA for VentFree 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 benefits and risks of VentFree?

Potential benefits of VentFree:

- Treatment can start soon after intubation when patients may be sedated

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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- Reduction of potential wasting of the abdominal wall muscles
- Reduced time to weaning from mechanical ventilation
- 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 VentFree:

- Patient discomfort during treatment
- Elevated blood pressure during treatment
- Elevated respiratory rate during treatment
- Muscle soreness
- Skin irritation and burns beneath the electrodes

What are the alternatives to VentFree and the known and potential benefits and risk of such products?

Alternatives to VentFree that is authorized under this Emergency Use Authorization (EUA) are “traditional” methods of weaning from the ventilator 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:

- Non-invasive
- Healthcare provider familiarity with standard ventilator weaning strategies, including those 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 VentFree FDA-approved or cleared?

No. VentFree is not 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 the Emergency Use Authorization (EUA) mechanism.

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.
