

FACT SHEET FOR PATIENTS

Emergency Use of the AerosolVE Device

June 11, 2021

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because an AerosolVE Device will be used on you.

The AerosolVE Device is intended for use by health care providers (HCPs) as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of patients with suspected or confirmed diagnosis of COVID-19 when performing certain medical procedures, such as placing a breathing tube in your trachea (windpipe) to support your breathing and providing breathing treatments, or during patient transport within the hospital, during the COVID-19 pandemic.

This Fact Sheet contains information to help you understand the risk and benefits of using the AerosolVE Device as part of your care plan. After reading this Fact Sheet, if you have any questions or would like to further discuss the information provided, please talk to your healthcare provider.

For up to date information on COVID-19, please visit the Center for Disease Control and Prevention (CDC) Coronavirus Disease 2019 (COVID-19)

Webpage: <https://www.cdc.gov/COVID19>

What is the COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

What is the AerosolVE Device?

The AerosolVE Device is a portable negative pressure temporary isolation and procedural tent system. The AerosolVE Device's disposable tent unit will be placed over your upper body by your HCP. Your HCP may cut slits into the clear vinyl tent to allow for the HCP to have

direct access to treat you while you remain isolated. The HEPA filter at the base of the tent is connected to a fan by exhaust tubing. The fan will create a negative pressure air flow environment that will help protect the HCP from pathogenic biological airborne particulates.

The AerosolVE Device is limited to use in a hospital setting, including for patient transport for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician.

You have the option to refuse this device. However, your doctor may be recommending this device because an FDA-cleared device may not be available due to shortages caused by COVID-19. If you choose to decline use of this device, you should discuss any alternative options with your healthcare provider.

How does the AerosolVE Device work?

The AerosolVE Device has a fan connected to the device to create negative pressure and air flow. You will always receive supplemental oxygen while you are in the AerosolVE Device. Negative pressure inside the enclosure should help keep pathogenic biological airborne particulates from sneezes, coughs, and talking inside the enclosure. This should reduce the risk to HCP of becoming infected. The tent is clear to allow for visibility for the patient and HCP while containing pathogenic biological airborne particulates inside the tent.

Why will the AerosolVE Device be used as part of my care?

Your HCP has selected to use the AerosolVE Device for your COVID-19 treatment and care, because it allows doctors, nurses and other HCP to attend to you while reducing exposure to the virus that causes COVID-19. The AerosolVE Device tent will allow you to be comfortable on your hospital bed while health care providers treat you from outside of the tent.

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.

FACT SHEET FOR PATIENTS

Emergency Use of the AerosolVE Device

June 11, 2021

Coronavirus
Disease 2019
(COVID-19)

OCID-19

What are the known and potential risks and benefits of the AerosolVE Device?

Known and Potential Risks:

- Device malfunction may lead to oxygen deprivation of the patient and patient injury
- Failure of the device may also increase the risk of possible contamination of HCP, or increased risk of release of pathogenic biological airborne particulates to the local environment and possible contamination of people in the surrounding area
- Failure of the device to work properly may lead to inadequate oxygen levels in the patient's bloodstream, which could cause a condition known as hypoxia, or elevated carbon dioxide levels in the bloodstream and lead to a condition known as hypercarbia
- Device may interfere with procedures conducted on the patient
- Inappropriately assembled device may lead to failure of the device to properly isolate patient
- Accidental device folding or blockage of airflow inlets may result in patient injury
- Delayed emergency removal of the device may result in patient injury
- Patient may have an allergic reaction to device materials

Known and Potential Benefits:

- May prevent or minimize risk of HCP exposure to pathogenic biological airborne particulates
- May aid as an extra layer of barrier protection in addition to PPE
- May allow a potentially safer method to perform standard, non-invasive respiratory treatments by containing and evacuating pathogenic biological airborne particulates
- Ability to transport a suspected/confirmed COVID-19 patient inside a hospital without contaminating surroundings and other personnel

Is the AerosolVE Device Food and Drug Administration (FDA)-approved or cleared?

No. The AerosolVE Device is not FDA-approved or cleared. The FDA has authorized this use of the AerosolVE Device through an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

The United States FDA has made the AerosolVE Device available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The AerosolVE Device 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. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective for use by HCP as an extra layer of barrier protection in addition to PPE, to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients with suspected or confirmed COVID-19, at the time of airway management when performing airway-related medical procedures, or during certain transport of such patients within the hospital, during the COVID-19 pandemic.

The EUA for the AerosolVE Device is in effect for the duration of the COVID-19 declaration justifying emergency use of the product, unless terminated or revoked (after which the products may no longer be used).

What are the approved alternatives?

There are no approved available alternative devices. FDA has issued EUAs for other similar products that can be found at:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

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.