

FACT SHEET FOR PATIENTS

Emergency Use of the Airway Dome

July 24, 2020

**Coronavirus
Disease 2019
(COVID-19)**

You are being given this Fact Sheet because an Airway Dome device will be used on you.

This device is intended to be used by healthcare 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 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 to support your breathing and providing breathing treatments, or during patient transport within a hospital setting for temporary transfer only for direct admission within the hospital during the COVID-19 pandemic.

This Fact Sheet contains information to help you understand the benefits and risks of using the Airway Dome for preventing the spread of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your HCP.

For the most 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 COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, has now spread globally, including to 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 Airway Dome?

The Airway Dome is a single-use, transparent covering which extends around your head, neck, and shoulders

and is attached to your chest with skin-safe adhesive tape. Two pairs of access ports are built into the dome and allow for the HCP to have access to you while you remain isolated. The Airway Dome provides a negative pressure environment around you using vacuum and medical air or oxygen to help protect the HCP from pathogenic biological airborne particulates.

The Airway Dome 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 product. If you choose to decline use of this device, you should discuss any alternative options or questions/concerns with your health care provider.

How does the Airway Dome work?

Suction and medical air or oxygen are connected to the Airway Dome to create negative pressure and deliver oxygen, respectively. 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.

What are known and potential benefits and risks with the Airway Dome?

Known and Potential Benefits

- Prevent/minimize risk of HCP exposure to COVID-19 by providing an extra layer of barrier protection in addition to PPE.
- Allow potentially safer method to perform standard, non-invasive respiratory treatments by containing pathogenic biological airborne particulates inside of the Airway Dome.

Known and Potential Risks

- Device malfunction may lead to oxygen deprivation of the patient and patient injury.

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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- Failure of the device may also increase the risk of possible contamination of HCP, or increased risk of release of pathogenic biological airborne particulates and possible contamination of people in the surrounding area.
- Allergic reaction to Airway Dome materials.
- Failure of the device to work properly may lead to inadequate oxygen levels in the bloodstream for the patient causing a condition known as hypoxia or elevated carbon dioxide levels in the blood stream in a condition known as hypercarbia.

What are the approved alternatives?

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

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

What is an Emergency Use Authorization (EUA)?

The US Food and Drug Administration (FDA) has made the Airway Dome available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Services' declaration that circumstances exist to justify the emergency use of medical devices, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.

The Airway Dome 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 the Airway Dome may be effective for use by HCPs as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by providing isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic, and the known and potential benefits of the Airway Dome, for such use outweigh the known and potential risks.

The EUA for the Airway Dome 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).

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