

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the **Airway Dome**. This device is authorized for use by healthcare providers (HCP) 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 hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

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**All patients who are treated with the Airway Dome will receive the Fact Sheet for Patients: *Emergency Use of the Airway Dome*.**

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#### 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.

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 Center for Disease Control and Prevention (CDC) webpage for the most up to date information (<https://www.cdc.gov/COVID19>).

#### What do I need to know about the emergency use of the Airway Dome?

- The Airway Dome is authorized for patient transport within a hospital setting for temporary transfer only for direct admission within the hospital, in the presence of a registered nurse or physician.
- Authorized non-transport use of Airway Dome is only for airway management (e.g., intubation, extubation and suctioning airways), or when performing any

airway-related medical procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or CPAP/BiPAP (continuous positive airway pressure /bi-level positive airway pressure) mask use, airway suctioning, percussion and postural drainage).

- The Airway Dome is intended to be used by HCPs in a hospital setting.
- The Airway Dome is not intended to replace PPE.
- Inspect Airway Dome prior to use. Any wear/tear of the chamber or other signs of degradation on the Airway Dome must promptly be reported to Ikonx, Inc. The healthcare facility must not use on patients, and must dispose of, such an Airway Dome.
- When using the Airway Dome on a patient:
  - Direct observation is required at all times
  - Use portable or wall-mounted medical air or oxygen.
  - When using the Airway Dome, patients should always be receiving supplemental oxygen.
  - Use continuous pulse oximetry and end-tidal CO<sub>2</sub> monitoring, if available.
  - Ensure all connections are tightly secured and checked frequently.
  - Position the patient in a temperature controlled environment to avoid hyper- and hypothermia.
  - Ensure the suction is connected to vacuum source that has either a High-Efficiency Particulate Air (HEPA) filter or the vacuum is part of a hospital wall suction system that evacuates the vacuumed air safely to the environment per institution's building codes and regulations.

Use appropriate PPE 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).

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#### What is the Airway Dome?

The Airway Dome is a single-use, transparent, negative pressure covering extending around the patient's head, neck, and shoulders. Two pairs of access apertures, sealed by non-latex gloves, are built into the dome and allow for isolated patient access by HCP. The negative pressure environment is generated via a portable suction or negative pressure pumps equipped with in-line HEPA filters or via the wall-mounted vacuum lines. The Airway Dome is authorized for use with supplemental oxygen, hospital vacuum lines, as well as portable vacuum pumps with in-line HEPA filters.

The Airway Dome is comprised of the following components:

- Collapsible dome frame
- Transparent plastic sheeting
- Two pairs of access apertures with latex-free gloves
- "Pass-through pouch" bag for inserting additional needed supplies or equipment
- Air ports with viral filter for airway circuitry -- supplemental oxygen, ventilation, and end tidal CO<sub>2</sub>
- Guarded ports for negative pressure and suctioning

The Airway Dome requires the following which is not provided:

- Skin-safe adhesive tape
- Wall-mounted vacuum pumps, or portable vacuum pump with in-line HEPA filter
- Portable or wall-mounted medical air or oxygen
- Anesthesia ventilator or bag valve mask
- In-line suction HEPA filter
- Anesthesia circuit viral filter
- In-line suction on/off valve
- End-tidal CO<sub>2</sub> line
- Suction tubing
- Endo-tracheal tube
- O<sub>2</sub> mask
- Nasal Cannula

All components of the Airway Dome are intended to be single-use and should be disposed after use. During transport of patients, the Airway Dome maintains

negative pressure via a portable vacuum pump with an in-line HEPA filter, and oxygenation is supplied via a portable medical oxygen tank.

#### Contraindications

The Airway Dome is not intended:

- For emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On individuals with communication disorders that might interfere with clinical care
- On children under 45 lbs

#### Warnings and Cautions

- Flammability of the Airway Dome has not been tested. No interventions that could create a spark or be a flammable source should be used within the Airway Dome.
- Remove the Airway Dome and use standard of care if there is difficulty visualizing or identifying anatomic landmarks or inability to intubate after the first try.
- Prolonged use of the Airway Dome may induce hypercarbia in a spontaneously breathing patient. In spontaneously breathing patients, the Airway Dome should only be used with medical air flow and suction both on and working, under direct observation, and with end-tidal CO<sub>2</sub> monitoring, if available. If end-tidal CO<sub>2</sub> monitoring is not available, then the use of the Airway Dome should be limited to no more than a short duration of time with medical air flow and suction both on and under direct observation
- Patients with diminished hearing may have difficulty understanding the provider while inside the Airway dome
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety
- Use of Airway Dome for patient transport must only occur within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. Maintenance of negative pressure with adequate air

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flow must be assured. All patients should be on supplemental oxygen. Patients must have continuous monitoring of pulse oxygen saturation (Sp-O<sub>2</sub>) levels, vital signs, EKG, and End-tidal CO<sub>2</sub>, if available, during transport.

#### **What are known and potential benefits and risks with the Airway Dome**

##### *Known and Potential Benefits*

- Prevent or minimize risk of HCP exposure to pathogenic biological airborne particulates.
- Aid as an extra layer of barrier protection in addition to PPE.
- Allow a potentially safer method to perform standard, non-invasive respiratory treatments by containing and evacuating pathogenic biological airborne particulates.

##### *Known and Potential Risks*

- Device malfunction may lead to hypoxia of the patient, patient injury and possible contamination of HCP, or increased risk of release of pathogenic biological airborne particulates to the local environment and possible contamination of personnel.
- Device malfunction may lead to hypercarbia in a spontaneously breathing patient.
- Device may interfere with procedures conducted on the patient.
- Allergic reaction to device materials.
- Failure of suction scavenger may result in increased risk of release of pathogenic biological airborne particulates to the local environment and possible contamination of personnel.

#### **What is an Emergency Use Authorization (EUA)?**

The United States 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' (HHS's) 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 HCP 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, or when performing airway-related medical procedures, or during transport of such patients during the COVID-19 pandemic.

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

#### **What are the approved available 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>.

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## How can I learn more?

### **CDC websites:**

**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>

### **FAQ on Personal Protective Equipment:**

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

### **FDA websites:**

**General:** [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus)

**EUAs:** <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

### **Manufacturer Information**

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