FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the Airborne Isolation Hood **April 13, 2021**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Airborne Isolation Hood. 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 temporary isolation of hospitalized patients with suspected or confirmed diagnosis of coronavirus disease 2019 (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.

All patients who are treated with the Airborne Isolation Hood should receive the Fact Sheet for Patients: Emergency Use of the Airborne Isolation Hood.

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). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. 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. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

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 Airborne Isolation Hood?

1. **Airborne Isolation Hood** 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. The patient should have constant monitoring of vital signs, electrocardiogram (EKG), oxygen saturation (SpO_2%), End tidal carbon dioxide ($EtCO_2$), if available, throughout transport. The maximum duration of use is 30 minutes if end-tidal CO_2 monitoring is not available, with inline blower fan on and under direct observation.
2. Authorized non-transport use of **Airborne Isolation Hood** 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 continuous positive airway pressure /bi-level positive airway pressure [CPAP/BiPAP] mask use, airway suctioning, percussion and postural drainage).
3. **Airborne Isolation Hood** is intended to be used by HCP in a hospital setting.
4. **Airborne Isolation Hood** is not intended to replace PPE or room sanitation and disinfection procedures.
5. Inspect **Airborne Isolation Hood** prior to use. Any wear/tear of the chamber or other signs of degradation must promptly be reported to **Airborne Isolation Hood** Medical Solutions Inc. The healthcare facility must not use on patients, and must dispose of, such **Airborne Isolation Hood**.
6. When using **Airborne Isolation Hood** on a patient:
   - Direct observation is required at all times
   - Use portable or wall-mounted oxygen.
   - When using **Airborne Isolation Hood**, patients should always be receiving supplemental oxygen.
   - Use continuous pulse oximetry and end-tidal CO_2 monitoring, if available.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

- Ensure all connections are tightly secured and checked frequently.
- Position the patient in a temperature-controlled environment to avoid hyper- and hypothermia.
- If the patient needs to be transported, the HCP may follow removal instructions, and either transport the patient without the hood as they would transport patients via standard protocol, or connect the hood to a portable battery pack which is available in hospitals.

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 HCP is available at the CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What is the Airborne Isolation Hood?
The Airborne Isolation Hood is a clear, rigid chamber made of transparent polycarbonate that covers a patient's head and upper body and then filters respiratory particles from the chamber using negative airflow, generated with an inline blower fan, through a HEPA filter. The hood has ports, sealed with silicon gaskets, through which the HCP's hands are passed to perform medical procedures, providing isolated access to the patient. There is also a small cutout at the bottom of the hood with a silicone barrier that acts as a cord feed through so that the hood can be removed without tangling cords attached to the patient. During transport, the hood must be used with a battery pack adequate to power the blower.

The Airborne Isolation Hood acts as an added layer of physical barrier in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients.

The Airborne Isolation Hood will be available to HCP and healthcare facilities.

The Airborne Isolation Hood is comprised of the following components:

- Respiratory Hood
- Exhaust hose-Clear Blo-R-Vac Duct Hose 4" ID; aluminum coated flexible hosing
- Blower Fan, 8-speed setting blower (AC Infinity CLOUDLINE S8)
- Levoit Air Purifier Filter; LV-H132XR
-
- Cleaning supplies (Isopropyl Alcohol or similar) per hospital protocol
- Securement devices (e.g., bungee cords or nylon rope)
- Optional plastic drape or covering for duct

The Airborne Isolation Hood requires the following which is not provided:

- Nasal Cannula
- Portable or wall-mounted oxygen
- Healthcare facility standard oxygen line (Standard 3/16" oxygen tubing)
- A blanket for the patient;
- Endo-tracheal tube
- O_2 mask

All components of The Airborne Isolation Hood are intended to be reusable. The HEPA filter and exhaust hose should be replaced every three months.

Contraindications
The Airborne Isolation Hood is not intended for use on:

- On patients needing 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 patients with anticipated or known history of claustrophobia and/or confined space anxiety
- On patients with communication disorders that might interfere with clinical care
- On patients under the age of 18
- On bariatric patients

- On patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure
- On patients requiring procedures that involve exceeding the maximum direct access slits or holes as stated in this IFU
- On patients in elderly care centers (non-hospital environment)
- On patients in ambulance transport
- Patients who are morbidly obese
- Pregnant women in the 2nd or 3rd trimester
- Individuals with certain communication disorders
- Children under 45 pounds(lbs.)

Warnings and Cautions

- Flammability of the Airborne Isolation Hood has not been tested. No interventions that could create a spark or be a flammable source should be used within the Airborne Isolation Hood.
- Remove the Airborne Isolation Hood and use standard of care if there is difficulty visualizing or identifying anatomic land marks or inability to intubate after the first try.
- Prolonged use of the Airborne Isolation Hood may induce hypercarbia in a spontaneously breathing patient. In spontaneously breathing patients, the Airborne Isolation Hood should only be used with medical air flow and suction both on and working, under direct observation, and with end-tidal CO_2 monitoring, if available.
- Patients with diminished hearing or communication disorders may have difficulty understanding the provider while inside the Airborne Isolation Hood.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/ or confined space anxiety
- Use of the Airborne Isolation Hood 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 flow must be assured. All patients should be on supplemental oxygen. Patients must have continuous monitoring of pulse oxygen saturation (Sp-O_2) levels, vital signs, EKG, and End-tidal CO_2, if available, during transport.
- Accidental device folding or blockage of air-ports may result in patient injury
- Delayed emergency removal of the device may result in patient injury

What are the known and potential benefits and risks of using the Airborne Isolation Hood?

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.

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.
- Delayed emergency removal of the device may result in patient injury
- Patient may have an allergic reaction to device materials.
- Failure of the blower system will cause negative pressure to be lost and the efficacy of the hood will be reduced to that of a simple plastic barrier.
- Strain to healthcare workers during placement or removal of hood – similar to other heavy equipment. Hospital protocols for lifting heavy equipment should be followed.
- The hood corners and arm insertion portals can tear or compromise PPE making the health care worker more susceptible to contamination
- The addition of the enclosure to established PPE may increase the cognitive load on the health care worker leading to an increased incidence of medical error while establishing an airway.

What is an EUA?

The United States Food and Drug Administration (FDA) has made the Airborne Isolation Hood available under an emergency access mechanism called 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 authorized use of the Airborne Isolation Hood 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, or 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 device that meets certain criteria for safety, performance, and labeling, and that it may be effective in treating patients with COVID-19.

The EUA for the Airborne Isolation Hood is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless the declaration is terminated or authorization is revoked (after which the products 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.

Where can I go for updates and more information?

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

Manufacturer Information
Aspire Air, Inc.
Minneapolis, MN 55442
612-518-7064

Contact:
Aspire Air, Inc.
Minneapolis, MN 55442
Customer Service: 612-518-7064

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**