

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the Duke University COVIAGE

September 24, 2020

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of COVIAGE. This device is authorized for use by healthcare personnel (HCP) as an extra layer of 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, when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

All patients who are treated with COVIAGE during the COVID-19 pandemic should receive the Fact Sheet for Patients: Emergency Use of COVID-19 Protective Barrier Enclosure (COVIAGE).

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 COVIAGE?

- COVIAGE is authorized for patient transport within a hospital setting for temporary transfer

(less than 40 minutes, at which time the battery may be depleted) 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), SpO₂% (oxygen saturation), End tidal carbon dioxide (EtCO₂), if available, throughout transport.

- The patient should always have supplemental oxygen during use of COVIAGE.
- COVIAGE is not intended to replace PPE or room sanitation and disinfection procedures.
- The use of COVIAGE may provide a greater level of protection for HCP during high-risk procedures involving manipulation of the airway, such as endotracheal intubations and in non-invasive respiratory care (such as high-flow nasal cannula oxygen, nebulizers and CPAP/ BiPAP).
- Inspect COVIAGE prior to use. Any wear/tear of the chamber or other signs of degradation on COVIAGE must be promptly reported to Duke University. The healthcare facility must dispose of and not use such COVIAGE on patients.

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 COVIAGE?

COVIAGE is a protective barrier enclosure that operates under a negative pressure gradient and filters pathogenic biological airborne particulates. The enclosure is supported by a reusable, adjustable aluminum frame, that fits most hospital beds and stretchers. The enclosure tent is constructed of a transparent, medical grade thermoplastic polyurethane (TPU) that is single patient use and disposable as

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medical waste. Negative pressure is created inside the enclosure by a reusable ventilation fan mounted at the head bracket of the hospital bed. The fan draws air in through an inlet at the top of the foot wall of the tent and exhausts air to the environment at the head wall of the tent after passing through High Efficiency Particulate Air (HEPA) filtration system, which uses two in-line filters to achieve HEPA-level filtration (99.999% filtration efficiency). The ventilation system comes with its own battery pack with 40-minute lifespan.

Medical personnel can attend to the patient inside COVIAGE by using sleeves with attached gloves, entry zippers, or a two-way access box through which medical supplies, food, water, etc. can be passed into and out of the tent. COVIAGE should always be used with PPE as recommended by the guidelines of your institution. It is recommended that a gown, gloves, mask, at a minimum, be used when using the glove ports.

The structure of the reusable aluminum frame allows for attachment to the bed and adaptability to different types and sizes of hospital unit beds as well as easy removal in emergency situations. The disposable TPU tent allows visibility for the patient and HCP and a barrier designed to keep pathogens inside the tent.

Contraindications

COVIAGE is not authorized for the following uses:

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

Warnings and Cautions:

- Remove COVIAGE and use the standard of care if there is difficulty performing medical care with the device in place.

- Do not place patients inside the enclosure unless the ventilation and filtration system is on and functioning properly.
- If the ventilation and filtration system fails during transport, unplug the battery pack and the fan. Visually inspect the fan, the power cord wires, and battery pack for damage. Check for a dead battery pack by connecting a freshly charged battery and turning on the power.
- If any punctures or tears in the tent are identified, do not use COVIAGE. Clean and disinfect undamaged, reusable components of COVIAGE and obtain new disposable components before proceeding.
- Do not keep patients in COVIAGE in direct sunlight.
- COVIAGE should be operated only in temperature and humidity-controlled environments to prevent temperature and humidity fluctuations that could interfere with patient thermal regulation and function of the filters.
- Monitor patient temperature continuously while the patient is in the unit.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety.
- COVIAGE should be checked for generation of negative pressure continuously (refer to operation instructions).
- COVIAGE includes single use components that must be properly disposed of following use to prevent spread of contamination.
- Inadequate cleaning and disinfection of COVIAGE reusable components between patient use may result in increased risk of transferring contaminants which may lead to infections.
- Inappropriately assembled device may lead to failure of the unit to properly isolate patient.
- This device does not protect against radiation, nor is it intended for use with any imaging modalities that preclude metals (e.g. MRI Use Prohibited).
- The electrical parts of this equipment have not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic

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- disturbances that may affect the performance of other equipment.
- Patient monitoring, wearable or implanted devices and their cables should be located as far as possible from the device motor; and their performance should be observed periodically to verify that they are operating normally during its operation.
- COVIAGE includes flammable materials. No interventions that could create a spark or be a flammable source should be used within COVIAGE.
- Prolonged use of COVIAGE with a nonfunctioning ventilation system and/or obstructed air intake may induce hypercarbia in a spontaneously breathing patient. Patients should be under direct observation, and with end-tidal CO₂ monitoring if available.
- COVIAGE should be used on spontaneously breathing or intubated patients with the ventilation system on and working, and the air intake unobstructed.
- 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.
- Patients must have continuous monitoring of pulse oxygen saturation (SpO₂), vital signs, EKG, and End-tidal CO₂ if available during transport.
- All patients should be receiving supplemental oxygen during COVIAGE use.
- Do not use COVIAGE on patients who suffer from noise sensitivity (a.k.a. hyperacusis) or other hearing disorders (e.g. phonophobia).

What are the known and potential benefits and risks of using COVIAGE?

Known and Potential Benefits

- May prevent or minimize risk of HCP exposure to pathogenic biological airborne particulates.
- May aid as an extra layer of protection in addition to PPE.

- May reduce the need for hospital negative pressure rooms for holding/triage of suspected/confirmed COVID-19 patients.
- 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 others in the surrounding area, or increased risk of release of pathogenic biological airborne particulates to the local environment and possible contamination of personnel.
- Inadequate cleaning and disinfection of COVIAGE reusable components between patient use may result in increased risk of disease transmission from contamination.
- Inappropriately assembled devices may lead to failure of the unit to properly isolate patient.
- Normal operation of the device may cause electromagnetic interference of the electrical parts of the device on patient's monitoring cables and devices, patient's implantable or wearable medical devices.

What is an EUA?

The United States Food & Drug Administration (FDA) has made the emergency use of COVIAGE available under an emergency access mechanism called an Emergency Use Authorization (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, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.

The COVIAGE 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, or available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the COVIAGE may be effective for use by HCP as an extra layer of barrier

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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 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>.

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-authorization>

Manufacturer Information

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