

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the **COVID-19 Airway Management Isolation Chamber** (hereafter referred to as the “CAMIC”). 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 during transport of patients, at the time of definitive airway management, or when performing medical procedures on such patients during the COVID-19 pandemic.

All patients who are treated with the CAMIC will receive the Fact Sheet for Patients: Emergency Use of the COVID-19 Airway Management Isolation Chamber (CAMIC).

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 CAMIC?

- The CAMIC is authorized for use by HCP as an extra layer of barrier protection in addition to PPE to

prevent HCP exposure to pathogenic biological airborne particulates during transport of patients, at the time of definitive airway management, or when performing medical procedures on such patients during the COVID-19 pandemic.

- The CAMIC is authorized for use by HCPs in US Army and Military Health Service (MHS) healthcare settings.
- The CAMIC is not intended to replace PPE.
- Inspect CAMIC prior to use. Any wear/tear of the chamber or other signs of degradation on the CAMIC must promptly be reported to US Army and the MHS; the healthcare facility must not use on patients and must dispose of such CAMIC.
- When using the CAMIC on a patient, the following is recommended:
 - Direct observation is required at all times
 - Use medical air
 - Use continuous pulse oximetry and end-tidal CO₂ 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 institutions 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).

What is the CAMIC?

The CAMIC system is a barrier device constructed by draping large clear plastic bag over a box-like frame

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**

made of common polyvinyl chloride (PVC) piping. The CAMIC consists of a PVC hollow frame and a clear large plastic (polyethylene) bag that is placed over the head, neck and shoulders of the patient to isolate airborne particulates. The CAMIC cycles out air through holes in the PVC frame. The CAMIC captures and removes particles emitted from a patient's nose and mouth using a flow of medical air, which comes in through holes in the PVC frame on one side and is sucked out by a vacuum on the other. The CAMIC is authorized for use with hospital vacuum lines, as well as portable vacuum pumps with in-line HEPA filters.

The CAMIC is comprised of the following components:

- Hollow, perforated PVC piping (reusable)
- Plastic (polyethylene) bag (disposable)
- Wall-mounted vacuum pump, or portable vacuum pump with in-line HEPA filter
- Portable or wall-mounted medical air.

The CAMIC is authorized for use during transport of patients. During transport of patients, the CAMIC maintains negative pressure via a portable vacuum pump with an in-line HEPA filter, and oxygenation is supplied via a portable medical air tank.

Contraindications

The CAMIC is not authorized for the following uses:

- 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 pounds (lbs)

Warnings and Cautions

- Flammability of the CAMIC has not been tested. No interventions that could create a spark or be a flammable source should be used within the CAMIC.
- Remove the CAMIC 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 CAMIC may induce hypercarbia in a spontaneously breathing patient. The CAMIC should only be used with a spontaneously breathing patient with medical air flow and suction both on and working, under direct observation, and with end-tidal carbon dioxide (CO₂) monitoring if available. If end-tidal CO₂ monitoring is not available, then the use of the CAMIC should be limited to no more than a short duration of time no longer than 30 minutes with medical air flow and suction both on and under direct observation
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety

What are known and potential benefits and risks with the CAMIC

Known and Potential Benefits

- Prevent or minimize risk of HCP exposure to the virus.
- Aid as an extra layer of barrier protection in addition to PPE.
- Allow a safer method for HCP 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.
- Inadequate disinfection of the CAMIC between patient uses may result in increased risk of disease transmission from contamination.

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

What is an Emergency Use Authorization (EUA)?

The United States Food and Drug Administration (FDA) has made the CAMIC 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, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.

The CAMIC 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 CAMIC 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 during transport or at the time of definitive airway management and performing medical procedures 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).

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

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