

## **Instructions for Healthcare Personnel (HCP): Use of the CAMIC**

The U.S. Food and Drug Administration (FDA) has authorized an Emergency Use Authorization (EUA) for the emergency use of the COVID-19 Airway Management Isolation Chamber (hereafter referred to as the CAMIC), to be used 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 with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing medical procedures during the COVID-19 pandemic.

The CAMIC is authorized for use by HCP as an extra layer of barrier protection to prevent HCP exposure to pathogenic biological airborne particulates; it is an adjunct to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE. The CAMIC has not been FDA-approved or cleared for this use; FDA authorized it for emergency use for the duration of the COVID-19 public health emergency (unless it is otherwise terminated or revoked sooner).

The CAMIC system is a barrier device constructed by draping a large clear plastic bag over a box-like frame 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 High-Efficiency Particulate Air (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 patient transport. During patient transport, 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.



**The instructions below are to assist in using the CAMIC. The CAMIC is not meant to be a stand-alone unit of PPE. The CAMIC should always be used with PPE recommended by your institution and pursuant to the guidance of your institution.**

**Inspect CAMIC prior to use. Any wear/tear of the chamber or other signs of degradation on the CAMIC must promptly be reported to U.S. Army Medical Research and Development Command (USAMRDC), the healthcare facility must not use on patients, and must dispose of such CAMIC.**

**All connections should be tightly secured and checked frequently. When a patient is within the CAMIC, direct observation is required.**

**Rx only**

**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 land marks 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 CO<sub>2</sub> monitoring if available. If end-tidal CO<sub>2</sub> 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

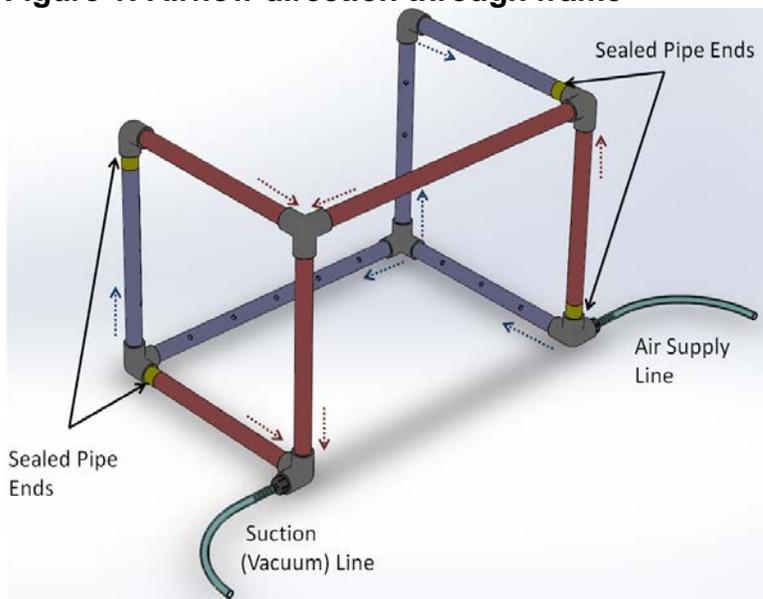
**CONTRAINDICATIONS:**

- 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.

**COVID-19 Airway Management Isolation Chamber (CAMIC) Instructions for Use**

- Secure a medical suction tubing to the vacuum outflow adaptor and then secure the medical air or oxygen tubing to the air inflow adaptor (Figure 1).
- Place large clear bag over frame (minimum size of 40" x 40"). If the bag has drawstrings, orient the bag such that the drawstring can be cinched around the shoulders / chest of the patient (Figure 2). If the bag does not have a drawstring, roll the edge of the excess bag (at least 3 inches) inward and tuck this excess gently around the patient's chest, shoulders and arms.
- Turn on medical air (use flow rate of 10L/Min) and suction (use pressure of 120 mmHg) prior to closure of drawstring.
- Ensure the suction is connected to vacuum source that has a HEPA/ultra-low particulate air (ULPA) filter or the vacuum is part of a hospital wall vacuum pump that evacuates the vacuumed air safely to the environment per institutions building code regulations.

**Figure 1: Airflow direction through frame**



**Figure 2: Final assembly, clear bag over frame**



### **Intubations using the CAMIC**

- **With patients inside the CAMIC, direct observation is required at all times.**
- **Use of continuous pulse oximetry and tidal CO<sub>2</sub> monitoring of the patient is highly recommended.**
- **Use medical air**
- **Tighten drawstring on bag snugly around the top of the patient's shoulders or chest to minimize leaks or if the bag does not have a drawstring, roll the edge of the excess bag (at least 3 inches) inward and tuck this excess gently around the patient's chest, shoulders and arms.**
- **Position the patient in a temperature-controlled environment to avoid hyper- and hypothermia.**
- After suction and air tubing are secured to the CAMIC's adaptors and turned on, pass the ventilator's airway circuit over chest of patient and pull drawstring snug or tuck the bag snug around the patient's chest.
- Using scissors, with care not to cut the patient, cut small holes in the panel of bag above the patient's head or where most comfortable for the operator, just large enough to allow the placement of the operator's hands within the CAMIC.
- Place endotracheal tube in accordance with institution Standard Operating Procedure.

## **Patient Transport using the CAMIC**

During patient transport, 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.

- With patients inside the CAMIC, direct observation is required at all times.
- Use of continuous pulse oximetry and tidal CO<sub>2</sub> monitoring of the patient is highly recommended.
- Obtain and use medical air/oxygen supplied via a portable compressed medical air or oxygen tank at air flow rates of 10 L/min.
- Obtain a portable vacuum pump with an in-line HEPA or ULPA filter and ensure connections are secure and place the suction levels of 120mmHg.
- Tighten drawstring on bag snugly around the top of the patient's shoulders or chest to minimize leaks or if the bag does not have a drawstring, roll the edge of the excess bag (at least 3 inches) inward and tuck this excess gently around the patient's chest, shoulders and arms.
- Position the patient in a temperature-controlled environment to avoid hyper- and hypothermia.
- Ensure the suction and air tubing are secured to the CAMIC's adaptors and turned on.
- After ensuring no immediate trip hazards such as excess overhanging tubing, the patient is ready for transport.

## **Emergency Removal Instructions**

***If the bag needs to be opened emergently the bag's drawstring can be loosened enough to allow removal of the bag over the frame or scissors can be used to cut the bag open. The operator and nearby personnel should be wearing appropriate maximal PPE, including an appropriately fitting N95 respirator in case of exposure to pathogenic biological airborne particulates or leave the area immediately if without appropriate PPE.***

**Figure 3: Endotracheal Intubation Procedure Using the CAMIC**



### **Disassembly**

- Discard plastic bag.
- To disinfect the frame, please refer to “Instructions for Healthcare Facilities: Assembly, Disassembly and Disinfection of the CAMIC” for instructions regarding proper disassembly and disinfection.