

# FACT SHEET FOR PATIENTS

Emergency Use of Covid-19 Airway Management Isolation Chamber (CAMIC) June 22, 2020

## Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because a COVID-19 Airway Management Isolation Chamber (hereafter referred to as the "CAMIC") will be used on you.

This device is intended 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 or when performing medical procedures during the COVID-19 pandemic.

This Fact Sheet contains information to help you understand the benefits and risks of using the CAMIC for treatment of patients during the COVID-19 pandemic. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

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**For the most up to date information on COVID-19, please visit the Center for Disease Control and Prevention (CDC) Coronavirus Disease 2019 (COVID-19) webpage:**

<https://www.cdc.gov/COVID19>

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### What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

### What is the CAMIC?

The CAMIC is a barrier device constructed by draping 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/covering that is placed over the head, neck and shoulders of the patient to isolate airborne droplets. The chamber cycles out air through holes in the PVC frame. The chamber captures and removes particles emitted from a patient's nose and mouth using a flow of air or oxygen, 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.

### How does the CAMIC work?

Suction and oxygen are connected to the CAMIC to create negative pressure and deliver oxygen, respectively. Negative pressure inside the enclosure should help keep particles from sneezes, coughs, and talking inside the enclosure.

### What are known and potential benefits and risks with the CAMIC?

#### *Known and Potential Benefits*

- Prevent/minimize risk of HCP exposure to the virus.
- Aids as an extra layer of protection in addition to PPE.
- Allow safer method for HCP to perform standard, non-invasive respiratory treatments by containing the airborne particulates inside of the CAMIC.

#### *Known and Potential Risks*

- Device malfunction may lead to patient oxygen deprivation
- The failure of the device may also increase the risk of release of the virus outside of the bag to contaminate HCP or people in the surrounding area
- Inadequate cleaning and disinfection of the CAMIC between patient use may result in increased risk of transferring contaminants which may lead to infections.
- Device malfunction may lead to excess carbon dioxide being built up in the bloodstream a condition known as hypercapnia in patients that are not being mechanically ventilated while within the CAMIC.

**How can I learn more?** The most up-to-date information on COVID-19 is available at the CDC General Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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

The FDA has made the CAMIC available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of 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 HCPs as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates during patient transport or at the time of definitive airway management and performing medical procedures during the COVID-19 pandemic, and the known and potential benefits of the CAMIC, for such use, outweigh the known and potential risks.

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

**How can I learn more?** The most up-to-date information on COVID-19 is available at the CDC General Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.