

FACT SHEET FOR PATIENTS

Emergency Use of the Duke University COVIAGE

September 24, 2020

**Coronavirus
Disease 2019
(COVID-19)**

You are being given this Fact Sheet because you will be placed in a COVID-19 protective barrier enclosure (hereafter referred to as COVIAGE).

COVIAGE is intended to be used 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 during transport or when performing certain medical procedures during the COVID-19 pandemic.

This Fact Sheet contains information to help you understand the known and potential risks and benefits of using COVIAGE. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

For 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>

What is the COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has 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 COVIAGE?

COVIAGE is a negative pressure protective enclosure that attaches to hospital beds and stretchers and filters pathogenic biological airborne particulates. COVIAGE is intended to be used by HCPs on patients like you to provide an extra layer of protection and help prevent HCP exposure to the virus when caring for, transporting,

or performing medical procedures on a patient who is known or suspected to have COVID-19.

COVIAGE protective barrier enclosure comprises an aluminum frame, a clear plastic tent, and a filtration/ventilation system. Negative pressure is created inside the enclosure by a reusable ventilation fan. The enclosure fits most hospital beds and stretchers. HCP can take care of you from outside COVIAGE using the gloves that are attached to the enclosure walls. Medical equipment and other items can be passed into (and out of) the enclosure without opening the enclosure entrance through the use of the zippered pass and a two-way access box.

COVIAGE is limited to use in hospital settings, including for patient transport for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician.

You have the option to refuse this product. If you choose to decline use of this device, you should discuss any alternative options or questions/ concerns with your healthcare provider.

How does the COVIAGE work?

COVIAGE has a ventilation and filtration system that draws air from outside the enclosure and exhausts air through two filters that capture bacteria and virus particles. Drawing air out of the enclosure creates negative pressure inside the tent that is intended to keep pathogenic biological airborne particulates from sneezes, coughs, and talking inside the tent and trapped in the filters. This should reduce the risk of HCP and other patients being exposed to these particulates.

The tent is clear to allow for visibility for the patient and HCP while containing pathogenic biological airborne particulates inside the tent. The ventilation system keeps the temperature inside the enclosure at room temperature.

What will I be able to do while inside the enclosure?

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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You will be able to lie down, sit up, eat, read, watch TV, receive appropriate medical care and do other things that you would normally do while in a hospital bed or stretcher.

What are the known and potential risks and benefits with 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.

Is the COVIAGE FDA-approved or cleared?

No, COVIAGE is not a U.S. Food & Drug Administration (FDA)-approved or cleared. The FDA has authorized this use of COVIAGE through an emergency access

mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

The US Food and Drug Administration (FDA) has made COVIAGE available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Services' 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.

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, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that COVIAGE 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 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, and the known and potential benefits of COVIAGE, for such use outweigh the known and potential risks.

The EUA for COVIAGE 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).

What are the approved alternatives?

There are no approved available alternative tests. FDA has issued EUAs for similar products that can be found at:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

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