FACT SHEET FOR PATIENTS

Emergency Use of a Protective Barrier Enclosure During the COVID-19 Pandemic (May 1, 2020)

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider (HCP) believes that it is necessary to provide you with treatment using a protective barrier enclosure. This device may be effective for use by the HCP when caring for or performing medical procedures on patients who are known or suspected to have COVID-19, in healthcare settings, to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment (PPE).

This Fact Sheet contains information to help you understand the risks and benefits of using this 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 HCP.

- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**
- **https://www.cdc.gov/COVID19**

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, has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19, but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What do I need to know about the emergency use of the protective barrier enclosure?

The protective barrier enclosure has been authorized under an Emergency Use Authorization (EUA) for emergency use by HCP when caring for or performing medical procedures on patients who are known or suspected to have COVID-19, in healthcare settings, to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE.

The virus that causes COVID-19 is highly contagious and the protective barrier enclosure provides an additional layer of protection when exposure to bodily fluids and airborne particles or droplets from COVID-19 patients is suspected. These products are intended to be used as a physical barrier by HCP in situations including, but not limited to, airway management (e.g., intubation, extubation, and suctioning of airways) and any aerosol generating procedures (e.g., nebulizer treatments, manipulation of oxygen mask or bilevel positive airway pressure (BiPAP) mask). During these medical procedures, the risk level of exposure to the virus is extremely high and these products can provide an additional layer of barrier protection for the HCP.

What is the protective barrier enclosure?

The protective barrier enclosure is typically made of transparent materials (e.g., acrylic, transparent polycarbonate sheet) and is designed to cover a patient's head and upper body. These products incorporate one or more ports through which the HCP's hands are passed to perform medical procedures. These are fairly simple products that do not include fans, air filters, or other features and not intended to generate negative pressure. These products should be removed if they impede ability to care for a patient, or impede the ability to perform a medical procedure on a patient, or impede the communication between HCP and patients.

How can I learn more? The most up-to-date information on the 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 are the known and potential benefits and risks of the protective barrier enclosure?

Potential benefits of the protective barrier enclosure:

- Decreases risk of HCP exposure to the virus
- Aids as an extra layer of barrier protection in addition to PPE
- Aids in performing standard, respiratory treatments by containing aerosolized particles during aerosol generating procedures (AGPs). AGPs potentially put healthcare personnel and others at an increased risk for pathogen exposure and infection, as they are more likely to generate higher concentrations of infectious respiratory aerosols than coughing, sneezing, talking, or breathing.
- Reduces potential for widespread distribution of virus in a busy trauma bay, emergency ward, or crowded critical care setting.

Potential risks of the protective barrier enclosure:

- Interferes with patient care. For example:
  - May result in increased risk of patient harm from airway compromise or loss in certain patients.
  - Compromised visualization of airway with failed intubation or loss of airway resulting in need for surgical airway
  - Hinders two way communication between HCP and the patient
- Cross contamination due to insufficient cleaning and disinfection after each use

Is the protective barrier enclosure FDA-approved or cleared?

No. The protective barrier enclosure is not approved or cleared by the United States Food and Drug Administration (FDA). No FDA-approved or cleared device should be used, when applicable and available.

Instead, FDA has made this device available under an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

The FDA has made certain devices available under an emergency access mechanism called an EUA. The EUA is supported by Secretary of Health and Human Services' (HHS) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The protective barrier enclosure, made available under an 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, including when there are no adequate, approved, available alternatives, and when based on the totality of scientific evidence available, it is reasonable to believe that a protective barrier enclosure may be effective.

The EUA for the protective barrier enclosure 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).

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