

FACT SHEET FOR HEALTHCARE PROVIDERS

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

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of a protective barrier enclosure during the COVID-19 pandemic.

All patients who are treated with a protective barrier enclosure will receive the Fact Sheet for Patients: Emergency Use of a Protective Barrier Enclosure During the COVID-19 Pandemic

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). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. 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 from 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose a risk for public health. Please check the CDC webpage for the most up to date information.

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

- Devices that meet certain conditions and criteria are authorized for emergency use.
- Protective barrier enclosures are authorized for emergency use by a healthcare professional (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).

- Healthcare providers should review the protective barrier enclosure labeling before use on a patient and follow the instructions for use.
- A protective barrier enclosure is not intended to replace the need for PPE.

Use appropriate PPE when caring for individuals suspected to have 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* on the Centers for Disease Control and Prevention (CDC) webpage <https://www.cdc.gov/media/releases/2020/s0501-covid-19-ipac.html>.

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).

When should a protective barrier enclosure be used?

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 are expected. 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 the virus transmission is extremely high and these products can provide an additional layer of barrier protection for the HCP. The patient's respiratory status and risk of difficult airway should be assessed prior to use of the protective barrier since it may interfere with securing an airway.

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

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

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- Aids as an additional 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:
 - Error in patient selection may result in increased risk of patient harm from airway compromise or loss.
 - Compromised visualization of airway may result in failed intubation or loss of airway resulting in need for surgical airway
 - Hinders two-way communication between the HCP and the patient
- Cross contamination due to inefficient cleaning and disinfection after each use

What is an EUA?

The United States Food and Drug Administration (FDA) has made the protective barrier enclosure available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service's determination that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages 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. However, in the absence of an FDA-approved or cleared alternative and based on the totality of scientific evidence, it is reasonable to believe the protective barrier enclosure

may be effective to use by HCPs 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. This EUA is in effect for the duration of the COVID-19 pandemic, unless terminated or revoked under which the device may no longer be used).

An FDA approved or cleared device should be used instead of the protective barrier enclosure under EUA, when applicable and available.

Where do I go for updates and more information?

CDC webpages:

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>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs: (includes links to patient fact sheet and manufacturer's instructions) <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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