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 2-14 days.

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

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

- 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 according to 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 (CDC) webpage (see links provided in “Where can I go for updates and more information” section).

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
**FACT SHEET FOR HEALTHCARE PROVIDERS**

**Emergency Use of a Protective Barrier Enclosure During the COVID-19 Pandemic**

May 1, 2020

- 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 with failed intubation or loss of airway resulting in need for surgical airway.
  - Hinders two-way communication between the HCP and the patient.

**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 declaration 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 used by HCP when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 in healthcare settings for prevention of exposure to pathogenic biologic 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 (in which the device may no longer be used).

Where can I go for updates and more information?

**CDC web pages:**
- General: [https://www.cdc.gov/COVID19](https://www.cdc.gov/COVID19)

**FDA web pages:**
- General: [www.fda.gov/novelcoronavirus](https://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](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)

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