Protective Barrier Enclosure

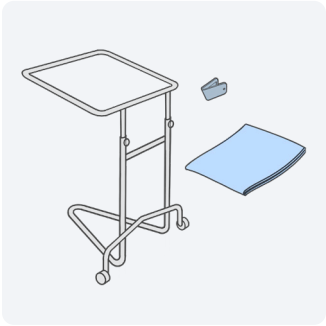
Quick Reference Guide

1 Gather Needed Materials

[1] Supplied plastic drape from carton that will form the barrier

[1] Mayo stand without tray

[1] Clamp



2 Open Drape Completely

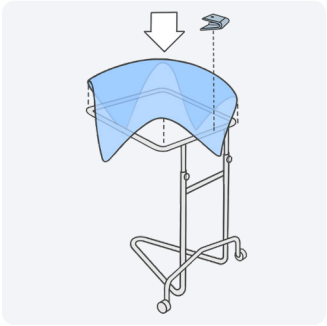
Unfold then unpeel the drape to open it completely.

3 Orient Drape to Mayo Stand

Position drape on Mayo stand in diamond orientation.

Confirm drape hangs down evenly on all sides of Mayo stand to form the protective barrier enclosure.

Clamp drape to Mayo stand.

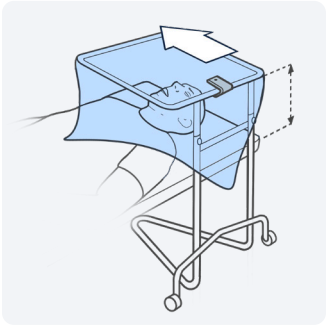


4 Position Mayo Stand Over Patient

Set Mayo stand height to provide sufficient workspace for procedure.

Secure Mayo Stand height adjustment knob.

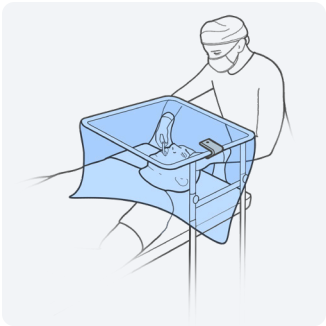
Position Mayo stand over patient head and torso.



5 Use Protective Barrier Enclosure During Procedure

Stand at appropriate position (e.g. patient head) to access patient airway.

Reach arms under drape for procedure.



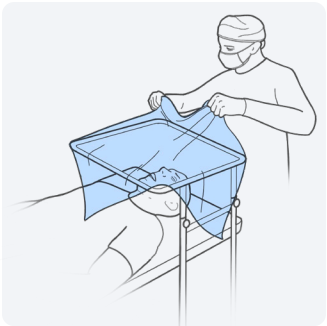
6 Dispose of Drape and Clean Mayo Stand

Remove clamp.

Lift drape off Mayo stand, then fold it to ensure droplets are contained.

Safely dispose of drape per hospital protocols.

Clean Mayo stand and clamp per hospital protocols.



Protective Barrier Enclosure

Important Information

For distribution & use only during the COVID-19 public health emergency while circumstances justify authorization of such emergency use.

Cleaning, Disinfecting, and Inspecting

This protective barrier enclosure is not provided sterile, and is not intended to be sterilized. Inspect this barrier before each use, and discard immediately if any tear or damage to the barrier is noted.

Contact Information

Please send feedback, including improvement requests to: PPE@intuitive-foundation.org

CAUTION
The patient should be assessed for respiratory status and difficult airway prior to device use.

CAUTION
Examine the protective barrier enclosure carefully before use and after securing the barrier on the Mayo stand. The barrier should not be used if any tears, discoloration, defects, or damage are identified.

CAUTION
Do not use this protective barrier enclosure where special access to the patient is needed.

CAUTION
Do not use this protective barrier enclosure if visibility for access needed for the procedure would be obstructed by use of the plastic drape.

CAUTION
Do not use this protective barrier enclosure without appropriate personal protective equipment (PPE).

CAUTION
Do not use Mayo stands with a horizontal crossbar that may prevent visibility and access to the patient airway.

CAUTION
Do not use the protective barrier enclosure with an unstable base. Using Mayo stands with a “U-Shaped” base can help ensure stability of the protective barrier enclosure during use.

CAUTION
Do not use protective barrier enclosure if it impedes ability to care for or communicate with patient, or impedes the ability to perform a medical procedure on the patient

Protective Barrier Enclosure

Device Description

This protective barrier enclosure is a transparent device designed to cover a patient's head and upper body under which the Health Care Professional's (HCP's) hands are passed to perform medical procedures. This protective barrier enclosure is being distributed pursuant to the Emergency Use Authorization (EUA) for protective barrier enclosures in response to the evolving COVID-19 pandemic issued on May 1, 2020. Specifically, the FDA has stated that protective barrier enclosures are authorized under this EUA when they are intended for use by Healthcare Professionals (HCPs) when caring for or performing medical procedures on patients who are known or suspected to have COVID-19 in healthcare settings, to help prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment (PPE). This product has not been FDA cleared or approved.

This protective barrier enclosure provides an extra layer of protection in addition to PPE. This protective barrier enclosure is not intended to replace PPE. The barrier does not include any fans, air filters, or other features and it is not intended to generate negative pressure.

This protective barrier is comprised of transparent materials to provide a clear, unobstructed view of the procedure field. The body contacting materials used in this protective barrier are listed below:

- Film: .007" thick, ester-based, Thermoplastic Polyurethane (TPU), manufactured by American Polyfilm
- This protective barrier does not include any drugs, biologics, microbial agents, or nanoparticles.
- This protective barrier is intended for **single use only and must be discarded after use**.

Additional Precautions

The Benefits/Risks of using a protective barrier enclosure device for airway management in certain populations should be predetermined by the HCP. These populations include but are not limited to:

- Patients requiring emergency endotracheal intubation who have severe respiratory compromise
- Patients with an anticipated or known history of difficult airway
- Patients who are morbidly obese
- Pregnant women in the 2nd or 3rd trimester
- Individuals with severe claustrophobia and/or confined space anxiety
- Individuals with certain communication disorders
- Patients with other anatomical abnormalities
- Patients with decreased neck mobility due to arthritis or other causes

Please see the two FDA May 1, 2020 fact sheets "Emergency Use of a Protective Barrier Enclosure During the COVID-19 Pandemic" for healthcare providers and patients.

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 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 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 of having 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* or on the Centers for Disease Control (CDC) webpage on *Infection Control*.

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

- 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
- Cross contamination due to insufficient 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 (HHS'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 for 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. This EUA is in effect for the duration of the COVID-19 pandemic, unless terminated or revoked (after 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 can 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

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**

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 device 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 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, and 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 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 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.

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,
  - o May result in increased risk of patient harm from airway compromise or loss in certain patients.
  - o Compromised visualization of airway with failed intubation or loss of airway resulting in need for surgical airway
  - o Hinders two way communication between the 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). An 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 the Secretary of Health and Human Services' (HHS's) 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).

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.