

FACT SHEET FOR PATIENTS

Emergency Use of Individual Biocontainment Unit (IBU)

September 8, 2021

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your healthcare provider will use an Individual Biocontainment Unit (hereafter referred to as the "IBU") on you.

This device is authorized to be used by healthcare personnel (HCP) as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of patients with suspected or confirmed diagnoses of COVID-19 when performing medical procedures, such as placing a breathing tube in your trachea to support your breathing and providing breathing treatments or during patient transport within a hospital setting for temporary transfer only with direct admission within the hospital during the COVID-19 pandemic.

This Fact Sheet contains information to help you understand the risks and benefits of using the IBU for preventing the spread of COVID-19. You have the option to accept or refuse use of this device. 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 Center for Disease Control and Prevention (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, has now spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat and new loss of taste or smell.

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.

What is the IBU?

The IBU is a negative pressure, clear, rigid chamber typically made of transparent materials (e.g., acrylic, transparent polycarbonate sheet) with aluminum framing that is designed to cover a patient's head and upper body. The IBU attaches to a standard hospital or surgical bed. A single sealable access window is built into the rear of the isolation chamber, which allows for isolated patient access. The negative pressure environment is generated within the Biocontainment Unit. The negative pressure environment is generated via a vacuum source equipped with an ultra-low particulate/high-efficiency particulate air filter. The IBU is limited to use in a hospital setting and only to be used in the presence of a registered nurse or physician.

How does the IBU work?

The enclosure is attached to a vacuum source which provides continuous negative pressure inside the enclosure; a battery-powered version of the vacuum source allows for patient transport while maintaining negative pressure within the enclosure. Negative pressure inside the IBU should help keep particles from sneezes, coughs, and talking inside the enclosure away from the HCP.

What are known and potential benefits and risks of the IBU?

Known and Potential Benefits:

- Prevent/minimize risk of HCP exposure to virus
- Provide an extra layer of barrier protection, in addition to PPE.
- Allow safer method for HCP to perform standard, non-invasive respiratory treatments by containing and evacuating the pathogenic biological airborne particulates inside the device.

Known and Potential Risks:

- Electromagnetic interference of the electrical parts of the device on patient's monitoring cables and devices, patient's implantable or wearable medical devices.
- Device malfunction may lead to excess carbon dioxide being built up in the bloodstream a

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condition known as hypercapnia in patients that are not being mechanically ventilated while within the IBU.

- Device malfunction may lead to patient oxygen deprivation
- Failure of the device may also increase the risk of release of the virus outside of the device to contaminate HCP or people in the surrounding area.
- Allergic reaction to non-biocompatible materials.
- Inadequate cleaning and disinfection of the IBU between patient uses may result in increased risk of transferring contaminants which may lead to infection.

What is an Emergency Use Authorization (EUA)?

The FDA has made the IBU 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 during the COVID-19 pandemic.

The IBU, 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 an IBU 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 particles during transport of patients with suspected or confirmed diagnosis of COVID-19, or at the time of definitive airway management, or performing medical procedures related to airway management and breathing treatments on such patients during the COVID-19 pandemic, and the known and potential benefits of the IBU, for such use, outweigh the known and potential risks.

The EUA for the IBU is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless the declaration is terminated or authorized revoked (after which the products may no longer be used).

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.

What are the approved alternatives?

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

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

How can I learn more?

CDC websites:

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>

FAQ on Personal Protective Equipment:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

FDA websites:

General: www.fda.gov/novelcoronavirus

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

To Report a Problem or for Assistance:

Product Sponsor/EUA Holder & Distributor:

Dr. J. Peter Rubin

University of Pittsburgh
Department of Plastic Surgery
Suite 6B Scaife Hall, Room 690
3550 Terrace Street
Pittsburgh, PA 15261
Phone: (412) 648-7677
E-mail: EAUBOX@pitt.edu

Manufacturer & Distributor:

Innovative Electronics Corporation

750 Trumbull Drive
Pittsburgh, PA 15205
Phone: (412) 276-0711
For Technical Assistance:

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E-Mail: Info@Innovelectronics.com

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