

FACT SHEET FOR PATIENTS

Emergency Use of the Patient Isolation Transport Unit (PITU)

May 8, 2020

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because you will be placed in a Patient Isolation Transport Unit (PITU). The PITU is intended for use by healthcare providers (HCP) for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID-19 infection requiring airborne or droplet isolation precautions 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 benefits and risks of using this PITU for preventing the spread of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

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 is the PITU?

The PITU is a protective negative pressure enclosure that attaches to standard hospital beds and gurneys. The PITU allows doctors, nurses, and other healthcare providers to attend to you while reducing exposure to the virus that causes COVID-19. It also may allow healthcare providers to move you safely while reducing risk of exposing others around you.

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.

The enclosure will allow you to be comfortable on your hospital bed while healthcare providers take care of you from outside the enclosure using the gloves that are attached to the enclosure walls. Equipment and other items can be passed into (and out of) the enclosure without opening the enclosure entrance through the use of the zippered pass through compartment on the side of the enclosure.

How does the PITU work?

The PITU has three ventilation motors that draw in fresh air from outside the enclosure and exhaust air through filters that may remove bacteria and virus particles. By drawing air out of the enclosure, a negative pressure is created inside the tent that should keep particles from sneezes, coughs, and talking inside the enclosure and then trapped in the exhaust filters. This should reduce the risk of healthcare providers from becoming infected.

What will I be able to do while inside the enclosure?

You will be able to lie down, sit up, eat, read, watch TV and do other things that you would normally do while in a hospital bed or gurney.

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

Known and Potential Benefits

Potential benefits of the PITU:

- Ability to transport suspected/confirmed COVID-19 patient inside a facility without contaminating surroundings and other personnel
- Reduction in the need for hospital negative pressure rooms for holding/triage of suspected/confirmed COVID-19 patients
- Aid as an additional layer of barrier protection in addition to PPE
- Patient will be able to lie down, sit up, eat, read, watch TV while in the PITU

Known and Potential Risks

Potential risks of the PITU:

- Device failure leading to loss of minimum required negative pressure and/or negative pressure

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differential to adjacent corridor which may result in increased risk of disease transmission

- Inappropriately assembled device may lead to failure of the unit to properly isolate patient
- Electromagnetic interference of the electrical parts of the device on patient's monitoring cables and devices, patient's implantable or wearable medical devices
- Device failure leading to an electrical hazard
- Device failure leading to a fire hazard

What is an EUA?

The United States FDA has made the emergency use of the PITU for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID-19 requiring airborne or droplet isolation precautions in healthcare settings to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.

The PITU has been made available under an EUA, and 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, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the PITU System may be effective for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID-19.

The EUA for the PITU 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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