FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the Patient Isolation Transport Unit (PITU) **May 8, 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 the 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 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).

All patients who are treated with the PITU during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of the Patient Isolation Transport Unit (PITU)

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 (https://www.cdc.gov/COVID19).

What do I need to know about the emergency use of thePITU?

- The PITU has been authorized for emergency use for temporary isolation and transport of patients with suspected or confirmed diagnosis of COVID-19 requiring airborne or droplet isolation precautions in healthcare settings. However, during the public health emergency, it would not be feasible to require HCPs to limit PITU use for patients with suspected or confirmed COVID-19; therefore, the authorization does not restrict use to such patients.
- The PITU is intended to be used by HCPs in a healthcare setting.
- These devices are not intended to replace PPE or room sanitation and disinfection procedures.
- These devices are not intended for use during surgical procedures.

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 CDC webpage on *Infection Control*. Current information on COVID-19 for HCPs is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What is the PITU?

The PITU is a negative pressure enclosure that attaches to standard hospital beds or gurneys. The enclosure is constructed of a flame retardant, clear, medical grade vinyl material that is single patient use and disposable as medical waste. The enclosure is suspended from a reusable, adjustable aluminum frame that fits most hospital beds or gurneys. Negative pressure is created inside the enclosure by three reusable battery-powered ventilation blower motors mounted at the top of the foot wall of the tent. The motors draw air in through vents at the foot of the tent and exhaust air to the environment at the head of the tent after passing through NIOSH-approved disposable High Efficiency Particulate Air (HEPA) filters. In addition, air is exhausted from the enclosure through disposable HEPA filters attached to the intake side of the blower motors. Each blower motor has its own battery with a nominal 8 hour life. For operation beyond nominal battery life, maintain a set of three freshly charged batteries.

Medical personnel can attend to the patient inside the PITU by using the glove ports located along the walls of

the enclosure. It is recommended that a gown and gloves be used when using the glove ports

Equipment, food, drink, reading material, 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.

Warnings and Cautions:

- Do not place patients inside the enclosure unless blower motors are on and blower exhaust air flow has been tested with a manometer.
- If a blower motor fails, turn off the power to the motor and unplug the battery pack. Visually inspect the motor and motor casing, power cord wires and power cord pins for damage. Check for a dead battery pack by connecting a freshly charged battery and turning on the power.
- If there are any punctures or tears to the enclosure identified, do not use the PITU. Clean and disinfect undamaged, reusable components of the PITU and obtain new disposable components before proceeding.
- Do not keep patients in the PITU in direct sunlight.
- The PITU should be operated only in temperature-controlled environments to prevent temperature fluctuations that could interfere with patient thermal regulation.
- Monitor patient temperature at frequent intervals while the patient is in the unit.
- The PITU should be checked for generation of negative pressure regularly (refer to set up instructions).
- Do not use in oxygen-enriched environments.
- The PITU is not intended to be used during surgical procedures.
- The PITU includes single use components which must be properly disposed of following use to prevent spread of contamination.

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 negative pressure 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 requiring airborne or droplet isolation precautions in healthcare settings.

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

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

Where can I go for updates and more information?

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

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