

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of ISOCUBE (ISOCUBE SS and ISOCUBE ONE)

May 3, 2021

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 ISOCUBE SS and ISOCUBE ONE (collectively ISOCUBE unless otherwise noted). This device is authorized for use by healthcare providers (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 hospitalized patients with suspected or confirmed diagnosis of coronavirus disease 2019 (COVID-19), at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

All patients who are treated with the ISOCUBE should receive the Fact Sheet for Patients: Emergency Use of ISOCUBE.

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). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. 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 Center for Disease Control and Prevention (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 ISOCUBE?

- ISOCUBE is authorized for patient transport within a hospital setting for temporary transfer only for direct admission within the hospital, in the presence of a

registered nurse or physician. The patient must have constant monitoring of vital signs, electrocardiogram (EKG), oxygen saturation (SpO₂%), End tidal carbon dioxide (EtCO₂), if available, throughout transport. If end-tidal CO₂ monitoring is not available, the maximum duration of use is 30 minutes with inline blower fan on and under direct observation.

- Authorized non-transport use of ISOCUBE is only for airway management (e.g., intubation, extubation and suctioning airways), or when performing any airway-related medical procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or continuous positive airway pressure /bi-level positive airway pressure [CPAP/BiPAP] mask use, airway suctioning, percussion and postural drainage).
- ISOCUBE is intended to be used by HCP in a hospital setting.
- ISOCUBE is not intended to replace PPE or room sanitation and disinfection procedures.
- Inspect ISOCUBE prior to use. Any wear/tear of the chamber or other signs of degradation on the ISOCUBE must promptly be reported to Prep Tech, LLC. The healthcare facility must not use on patients, and must dispose of, such an ISOCUBE.
- When using ISOCUBE on a patient:
 - o Direct observation is required at all times.
 - o Use portable or wall-mounted oxygen.
 - o When using ISOCUBE™, patients must always be receiving supplemental oxygen.
 - o Use continuous pulse oximetry and end tidal CO₂ monitoring, if available.
 - o Ensure all connections are tightly secured and checked frequently.
 - o Position the patient in a temperature-controlled environment to avoid hyper-and hypothermia.
 - o Ensure the suction is connected to vacuum source that has either a High-Efficiency Particulate Air (HEPA) filter (0.3 µm particulates or better) or the vacuum is part of a hospital wall suction system that evacuates the vacuumed air safely to the environment per institutions building codes and regulations.

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**

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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 HCP is available at the CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What is ISOCUBE?

ISOCUBE SS and ISOCUBE ONE are negative pressure chambers that attach to a standard hospital or surgical bed or stretchers and extends around the patient's head, neck, and shoulders. Both devices use a single-use, clear, negative pressure isolette chamber that is discarded between uses. Four integrated gloves are built into the chamber to allow for isolated patient access. The ISOCUBE SS stainless-steel base and rail system is sanitized between uses. The ISOCUBE ONE frame is single use and completely discarded along with the negative pressure isolette chamber between uses. The negative pressure environment is generated via wall-mounted hospital vacuum lines or negative pressure pumps equipped within-line HEPA filters. ISOCUBE acts as an added layer of physical barrier in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients.

ISOCUBE will be available to HCP and healthcare facilities.

ISOCUBE is comprised of the following components:

- Collapsible rigid coated-steel frame (ONE) and detachable stainless-steel base/rails (SS)
- Transparent plastic isolette barrier enclosure
- Detachable drape
- Four arm access holes with integrated gloves built directly onto the isolette
- Foam portal with microperforated tubing holes for penetration into the isolette and connecting hospital suction lines to either wall-mounted vacuum pump(s) or portable vacuum pump(s) with in-line HEPA filter(s)

ISOCUBE requires the following, which is not provided:

- Wall-mounted vacuum pump(s) or portable vacuum pump(s) with in-line HEPA filter(s) (0.3µm or better filtration)
- Healthcare facility standard suction hose lines (Minimum 1/4" suction tubing)
- Nasal Cannula
- Portable or wall-mounted oxygen
- Healthcare facility standard oxygen line (Standard 3/16" oxygen tubing)
- A blanket for the patient
- Endo-tracheal tube
- O₂ mask

All components of ISOCUBE ONE are single-use and must be discarded after use. ISOCUBE SS base and rails are multi-use and must be sanitized after each use. Both devices use a single-use, clear, negative pressure isolette chamber that is discarded between uses. During transport of patients, ISOCUBE maintains negative pressure via portable vacuum pump(s) with in-line HEPA filter(s), and oxygenation is supplied via a portable medical oxygen tank.

Contraindications

ISOCUBE is not intended for use on:

- Patients needing emergent endotracheal intubation with severe hypoxemia
- Patients with anticipated or known history of difficult airway
- Patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- Patients with communication disorders that might interfere with clinical care
- Children under 45 lbs Patients with anticipated or known history of claustrophobia
- Bariatric patients
- Patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure
- Patients in elderly care centers (non-hospital environment)
- Patients in ambulance transport.

Warnings and Cautions

- Flammability of ISOCUBE has not been tested. Do not perform interventions that could create a spark or be a flammable source within the ISOCUBE.

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- Remove ISOCUBE and use standard of care if there is difficulty visualizing or identifying anatomic landmarks or inability to intubate after the first try. Prolonged use of the ISOCUBE may induce hypercarbia in a spontaneously breathing patient. In spontaneously breathing patients, ISOCUBE must only be used with medical air flow and suction both on and working, under direct observation, and with EtCO₂ monitoring, if available.
- Patients with diminished hearing or communication disorders may have difficulty understanding the provider while inside the ISOCUBE.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety.
- Use of ISOCUBE for patient transport must only occur within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. Maintenance of negative pressure with adequate air flow must be assured. All patients must be on supplemental oxygen. Patients must have continuous monitoring of SpO₂% levels, vital signs, EKG, and End-tidal CO₂, if available, during transport.
- Accidental device folding or blockage of air-ports may result in patient injury.
- Delayed emergency removal of the device may result in patient injury.

What are the known and potential benefits and risks of using ISOCUBE?

Known and Potential Benefits

- May prevent or minimize risk of HCP exposure to pathogenic biological airborne particulates as an extra layer of barrier protection.
- May allow a potentially safer method for the HCP to perform standard, non-invasive respiratory treatments by containing and evacuating pathogenic biological airborne particulates.

Known and Potential Risks

- Device malfunction may lead to hypoxia of the patient, patient injury and possible contamination of HCP, or increased risk of release of pathogenic biological airborne particulates to the local environment and possible contamination of personnel.
- Device malfunction may lead to hypercarbia in a

spontaneously breathing patient.

- Device may interfere with procedures conducted on the patient.
- Accidental device folding or blockage of air-ports may result in patient injury
- Delayed emergency removal of the device may result in patient injury
- Patient may have an allergic reaction to device materials.

What is an Emergency Use Authorization (EUA)?

The United States Food and Drug Administration (FDA) authorized use of ISOCUBE under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The authorized use of ISOCUBE under this 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, which includes that there are no adequate, approved, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the device may be effective in protecting HCP when performing certain respiratory treatments during the COVID-19 pandemic, and the known and potential benefits outweigh the known and potential risks for such use.

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

What are the approved available alternatives?

There are no approved available alternative devices as an extra layer of barrier protection for HCPs. 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>.

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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>

Manufacturer Information

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