

Instructions for Healthcare Providers and Facilities: ISOCUBE™ ONE

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for ISOCUBE ONE, for use by healthcare providers (HCP) as an additional 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 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.

Authorized non-transport use of ISOCUBE ONE is only for definitive 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), or during certain patient transport. Authorized use of ISOCUBE ONE during patient transport is only within a hospital setting for temporary transfer with 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. For all authorized uses, the patient must always have supplemental oxygen during use of ISOCUBE ONE. If end-tidal CO₂ monitoring is not available, limit the duration of transport to 30 minutes with inline blower fan on and under direct observation.

ISOCUBE ONE has not been FDA-approved or cleared for this use; ISOCUBE ONE has been authorized for emergency use by FDA under an EUA. ISOCUBE ONE has been authorized only for the duration of the COVID-19 public health emergency declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

HCP must follow these instructions, as well as procedures at their healthcare facility to use ISOCUBE ONE.



The instructions below are to assist in using ISOCUBE ONE. ISOCUBE ONE is an adjunctive protective barrier designed to mitigate risk to HCP. ISOCUBE ONE is not meant to be a stand-alone unit of PPE. ISOCUBE ONE must always be used with appropriate PPE and pursuant to the guidance of your institution.

All connections must be tightly secured and checked frequently. Any time anyone is within ISOCUBE ONE, direct observation is required. Inspect ISOCUBE ONE prior to use. Any wear/tear of the chamber or other signs of degradation on ISOCUBE ONE must promptly be reported to Prep Tech, LLC. The healthcare facility must not use on patients and must dispose of such a ISOCUBE ONE. Rx Only.

WARNINGS:

- Flammability of ISOCUBE ONE has not been tested. Interventions that could create a spark or be a flammable source must not be used within ISOCUBE ONE.
- Remove ISOCUBE ONE 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 ISOCUBE ONE may induce hypercarbia in a spontaneously breathing patient. ISOCUBE ONE must be used with medical air flow and suction both on and working, under direct observation, and with EtCO₂ monitoring if available.
- 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%, vital signs, EKG, and EtCO₂ if available during transport.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety.
- When using ISOCUBE ONE, patients must always be receiving supplemental oxygen.
- Patients with diminished hearing may have difficulty understanding the provider while inside ISOCUBE ONE.
- The ISOCUBE ONE is a single-use device and must be disposed of following the disposal instructions after use.
- If ISOCUBE ONE is accidentally folded or the air-ports are blocked, this may result in patient injury.
- Delay in removing a patient from the device in the event of an emergency removal may result in patient injury.

CONTRAINDICATIONS:

ISOCUBE ONE is not authorized 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.

ISOCUBE ONE INSTRUCTIONS FOR USE

Device Description:

ISOCUBE ONE is a single-use, clear, negative pressure chamber that attaches to a standard hospital or surgical bed, or stretchers and extends around the patient's head, neck, and shoulders. Access holes with four (4) integrated gloves, are built into the chamber to allow for isolated patient access. The negative pressure environment is generated via wall-mounted hospital vacuum lines or 1-2 negative pressure pumps equipped with in-line high- efficiency particulate air (HEPA) filter(s). The ISOCUBE ONE unit acts as an added layer of physical barrier in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates. ISOCUBE ONE will be available to HCP and healthcare facilities.

Items You Will Need:

- ISOCUBE ONE Device
- 1 or 2 Facility Wall-Mounted Pressure Regulators (capable of maintaining continuous high suction at 200mmHg to produce 30 LPM per line) OR Portable Vacuum Pump(s) (capable of maintaining continuous high suction at 200mmHg to produce 30 LPM per line) with Inline HEPA Filter(s) (single use only; 0.3 µm or better filtration)
- 1 Facility Wall-Mounted Oxygen Delivery Regulator
- 1 or 2 Healthcare Facility Standard Suction Hose Lines (minimum 1/4"ID) (Single Use Only)
- 1 Healthcare Facility Standard Oxygen Line (usually 3/16"ID) (Single Use Only)
- 1 Blanket for Patient
- Endotracheal tube
- Nasal cannula
- Oxygen mask

ISOCUBE ONE Device Components:

- (1) ISOCUBE Collapsible Metal Frame
- (1) ISOCUBE ONE Clear Plastic Isolette Negative Pressure Chamber



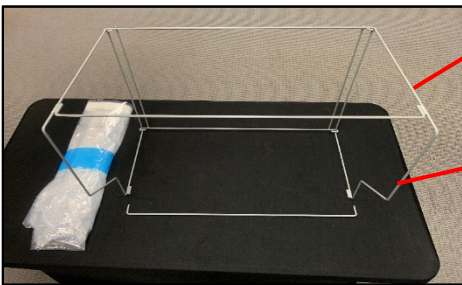
ISOCUBE frame and isolette in packaging folded flat



ISOCUBE Drape

ISOCUBE Isolette

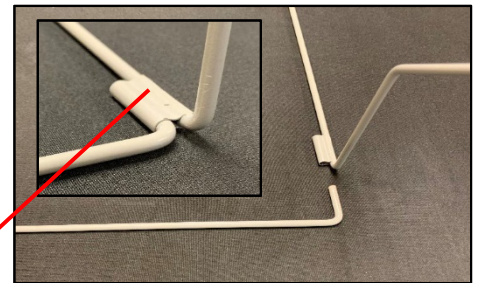
1. Remove all ISOCUBE™ ONE components from the shipping box. Open protective plastic to expose the coated metal frame, two metal frame braces (rods with 90-degree end-bends) and isolette packaging.
2. Remove the isolette (has foam and white tape border) and drape from its packaging. Set small folded drape aside.
3. Fold open both sides of the wire frame orienting the rail bends as shown. The patient side bends in the rails make room for patient's arms/shoulders.
4. Insert the two (top and bottom) wire frame braces into their respective four (4) cavities with bends facing away from the patient side of the unit.



Unfold arms 90 degrees, attach top and bottom brace rails in four (4) slots

Rail bends. Patient side of ISOCUBE

Proper insertion of brace rail into slot



5. Position the plastic isolette opening (white tape on 3 sides) onto the non-bent (HCP side) of the frame. Slide the plastic isolette completely over the frame and to the HCP side of the isolette. The white removable double-stick tape at the top of the isolette should extend just past the inserted top brace.



Slide isolette onto frame with bends facing down

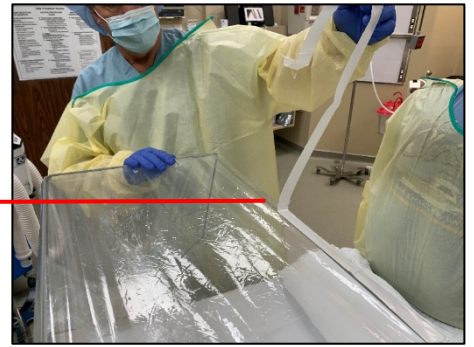
Finish pulling isolette onto frame





ISOCUBE ready for adhering the drape

Place on bed. Remove white tape to expose adhesive

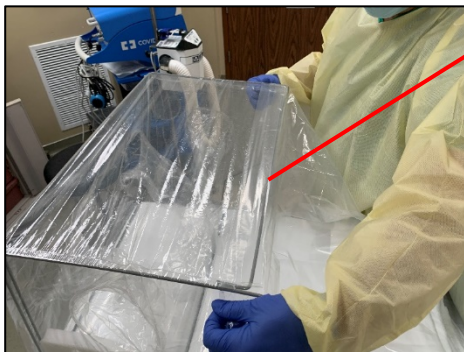


6. Completely remove all white tape on sides & top of ISOCUBE to expose adhesive.
7. Unfold the drape. With the long side of the drape folded in half, press approximately two inches of the drape edge along the adhesive starting on the top of ISOCUBE, then along the sides (drape sides will extend past the bottom of ISOCUBE).

Find center of long drape side by folding drape in half



8. Roll adhered drape onto top of ISOCUBE ready to be unfurled onto patient.



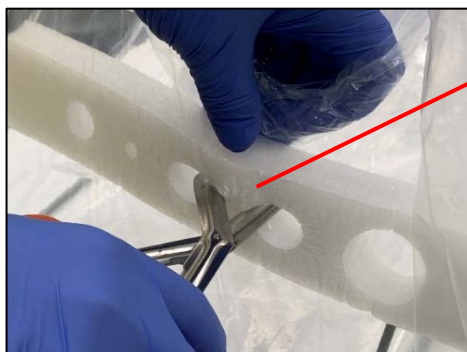
Center and press drape onto ISOCUBE adhesive on top and sides

ISOCUBE and drape ready for patient



Preparing ISOCUBE™ ONE for a Patient

1. Place ISOCUBE above or below the bed mattress. Gather all instruments/tools needed to perform a planned medical procedure and place them inside ISOCUBE towards the sides (leaving room in the center for the patient's head).
2. Route the oxygen delivery system (anesthesia or ventilator circuit tubing with EtCO₂, Ambu bag, etc.) through the white foam tubing portal of ISOCUBE. Perforated holes are provided for single or dual tubing circuits. The largest hole fits a standard single tubing circuit. If using a dual tube system, use scissors to cut a slit between the foam holes before inserting the tubing.



Using scissors to cut between holes for a dual tubing ventilator circuit.



Inserting ventilator circuit through foam.

3. Insert the end of one or more vacuum sources (wall suction, Neptune, etc.) through the far left (22mm) foam port hole.
4. Route the oropharyngeal suction tubing into ISOCUBE through the second to last hole (3/8"), leaving ample length needed for suctioning the airway. Leave the oropharyngeal suction turned on to optimize vacuum flow.



22mm wall/Neptune, etc. suction portal

3/8" oropharyngeal suction portal hole

Dual tubing ventilator circuit through foam



Applying the Drape to a Patient

1. The patient's head should be inserted into ISOCUBE a few inches from the bottom frame rail on the HCP side of the unit. Once inside, quickly secure the patient's airway for the appropriate medical procedure (CPAP, BiPAP, etc.).
2. Unfurl the drape and lay the long end across the patient's chest. Tuck the drape ends under the bedside mattress.



Patient inside ISOCUBE with secure airway.

Drape laid across patient chest & tucked under the mattress



Notes:

- Room air is drawn into ISOCUBE (**BLUE** arrows) under the drape edge and sides then out through filtered suction.
- **Continuous drawn air through hospital supplied suction is required to generate negative pressure and to remove aerosolized droplets/particles that may contain harmful viruses or bacteria.**

Emergency Access to Patients inside ISOCUBE™ ONE



- **Opening ISOCUBE in an emergency situation can potentially expose HCP's to aerosolized droplets contained within ISOCUBE**
- **ALWAYS wear PPE with using ISOCUBE**

1. If direct access to the patient is needed, lift the drape while tucking it around back of the patient's head.
2. If more access is needed, use scissors or a knife to cut open the isolette or remove it completely as depicted in the next section of this document.



Lifting the drape for emergency access to patient

Emergency/Removal of ISOCUBE™ ONE

1. Have an alternative airway circuit on hand ready to put on the patient.
2. Slide the ISOCUBE away from the patient while keeping the loose drape end close to the patient's head.



Alternative airway ready for patient



Keep drape close to the patient's head. Put excess drape inside isolette

3. While keeping the drape attached to ISOCUBE, tuck the drape under the ISOCUBE base and place on a nearby cart or table. The isolette may contain harmful particles. Keep the isolette sealed as much as possible.
4. Secure a new airway for the patient and prepare to dispose of the isolette, frame, and other contaminated items.



Removing ISOCUBE with drape



Patient secured with new airway

ISOCUBE™ ONE Disassembly



- **ISOCUBE is used once and then discarded.**
- **The ISOCUBE after use is a biohazard and requires proper disposal per facility standard procedures..**
- **Full PPE must be worn at all times during disposal of ISOCUBE following the facility's policy and protocol for the disposal of biohazard waste.**

1. Place contaminated items such as circulation/suction tubing used during the medical procedure inside the isolette.
2. Remove wire frame braces from their slots and lay them inside the isolette.
3. Fold isolette and all contaminated items into a large wad, using the “room-exposed side of the drape” on the outside of the wad.
4. Dispose of all items following the facility’s policy and protocol for disposal of biohazard waste.



Remove top and bottom brace rails. Fold ISO-CUBE flat with all contaminated circuits, tubing, etc. inside the isolette.

Isolette, drape and all contaminated items folded into a large wad.



Dispose isolette, drape, metal rails, and all contaminated items per institutional instructions for biohazard waste.

