

Instructions for Healthcare Facilities: Assembly and disposal of Airway Dome.

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the Airway Dome, 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 isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

Authorized non-transport use of Airway Dome 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 CPAP/BiPAP (continuous positive airway pressure/bi-level positive airway pressure) mask use, airway suctioning, percussion and postural drainage). Authorized use of the Airway Dome 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 should have constant monitoring of vital signs, electrocardiogram (EKG), SpO₂% (oxygen saturation), End tidal carbon dioxide (EtCO₂) if available throughout transport. For all authorized uses, the patient should always have supplemental oxygen during use of the Airway Dome.

The Airway Dome has not been FDA-approved or cleared for this use; The Airway Dome has been authorized only for the duration of the 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 authorization is terminated or revoked sooner.

HCP should follow these instructions, as well as procedures at their healthcare facility, to use the Airway Dome.



The instructions below are to assist in build, assembly and disposal of Airway Dome. The Airway Dome is an adjunctive protective barrier designed to mitigate risk to HCP. The Airway Dome is not meant to be a stand-alone unit of PPE. The Airway Dome should always be used with approved PPE and pursuant to the guidance of your institution.

All connections should be tightly secured and checked frequently. Any time anyone is within the Airway Dome, direct observation is required. Inspect Airway Dome prior to use. Any wear/tear of the chamber or other signs of degradation on the Airway Dome must promptly be reported to IkonX, Inc. The healthcare facility must not use on patients, and must dispose of, such an Airway Dome.

Warnings

- **Flammability of the Airway Dome has not been tested. No interventions that could create a spark or be a flammable source should be used within the Airway Dome.**

- Remove the Airway Dome and use standard of care if there is difficulty visualizing or identifying anatomic land marks or inability to intubate after the first try.
- Prolonged use of the Airway Dome may induce hypercarbia in a spontaneously breathing patient. The Airway Dome should with medical air flow and suction both on and working, under direct observation, and with end-tidal CO₂ monitoring if available. If end-tidal CO₂ monitoring is not available, then the use of the Airway Dome should be limited to no more than a short duration of time with medical air flow and suction both on and under direct observation.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety.
- 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 should be receiving supplemental oxygen. Patients must have continuous monitoring of pulse oxygen saturation (SpO₂), vital signs, EKG, and End-tidal CO₂ if available during transport.
- When using the Airway Dome patients should always be receiving supplemental oxygen.
- Patients with diminished hearing may have difficulty understanding the provider while inside the Airway dome.
- Airway Dome is a single-use device and should be disposed of following the disposal instructions after use.

CONTRAINDICATIONS:

The Airway Dome is not authorized:

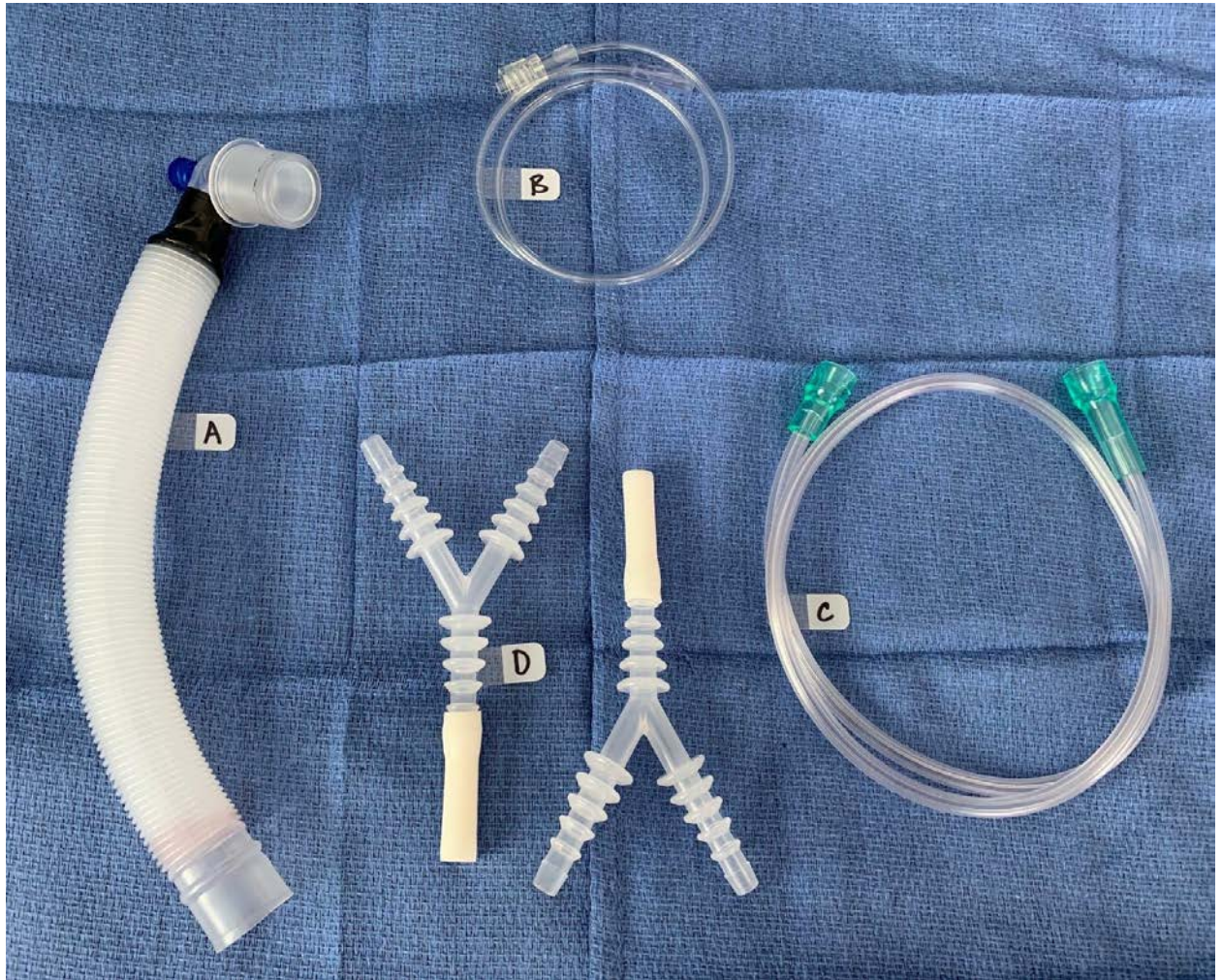
- For emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On individuals with communication disorders that might interfere with clinical care
- On children under 45 lbs.

Airway Dome Instructions on Build, Assembly, Disassembly, and Disposal

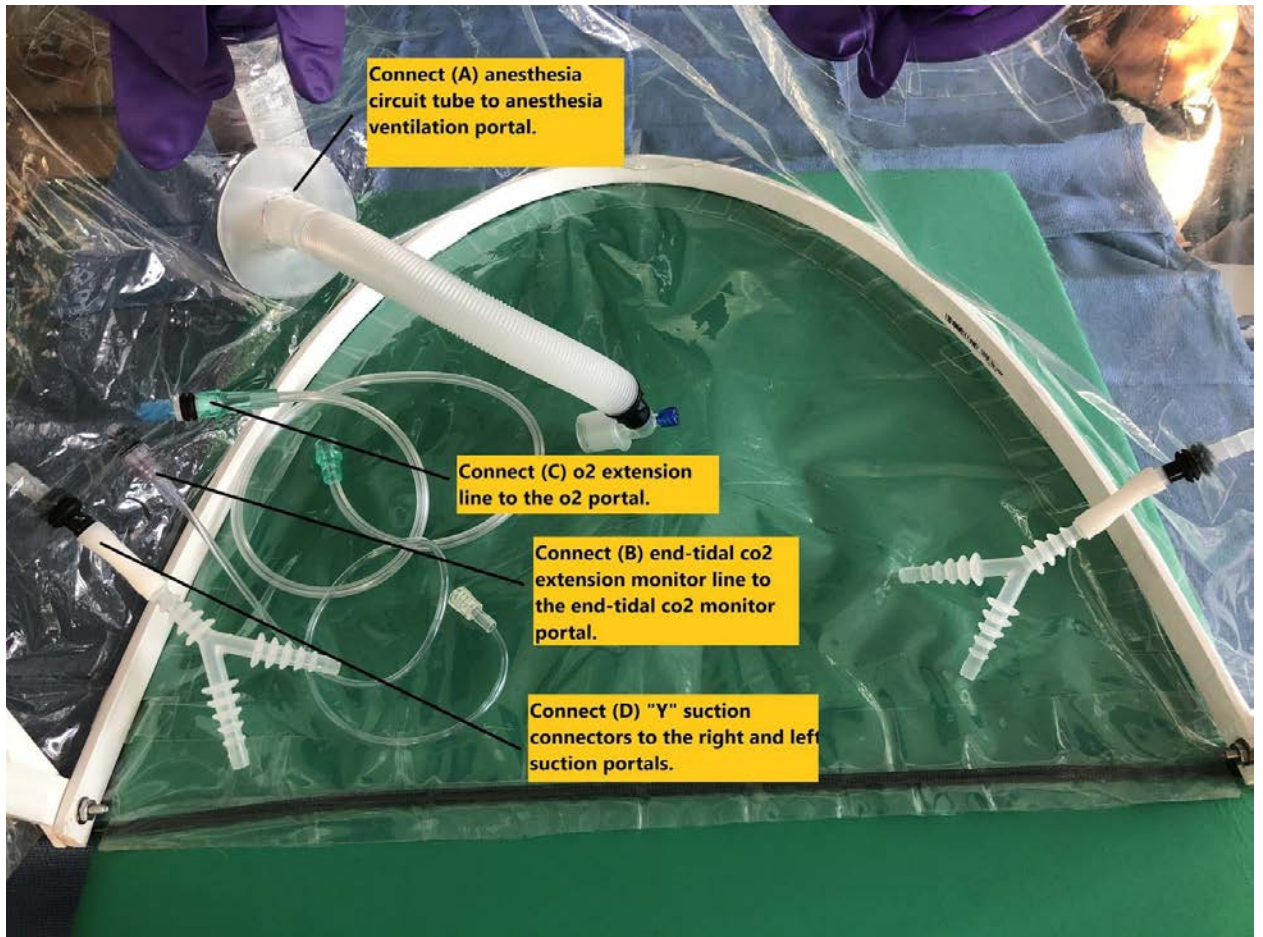
- Open and remove the Airway Dome from the package and place at the head of the bed.



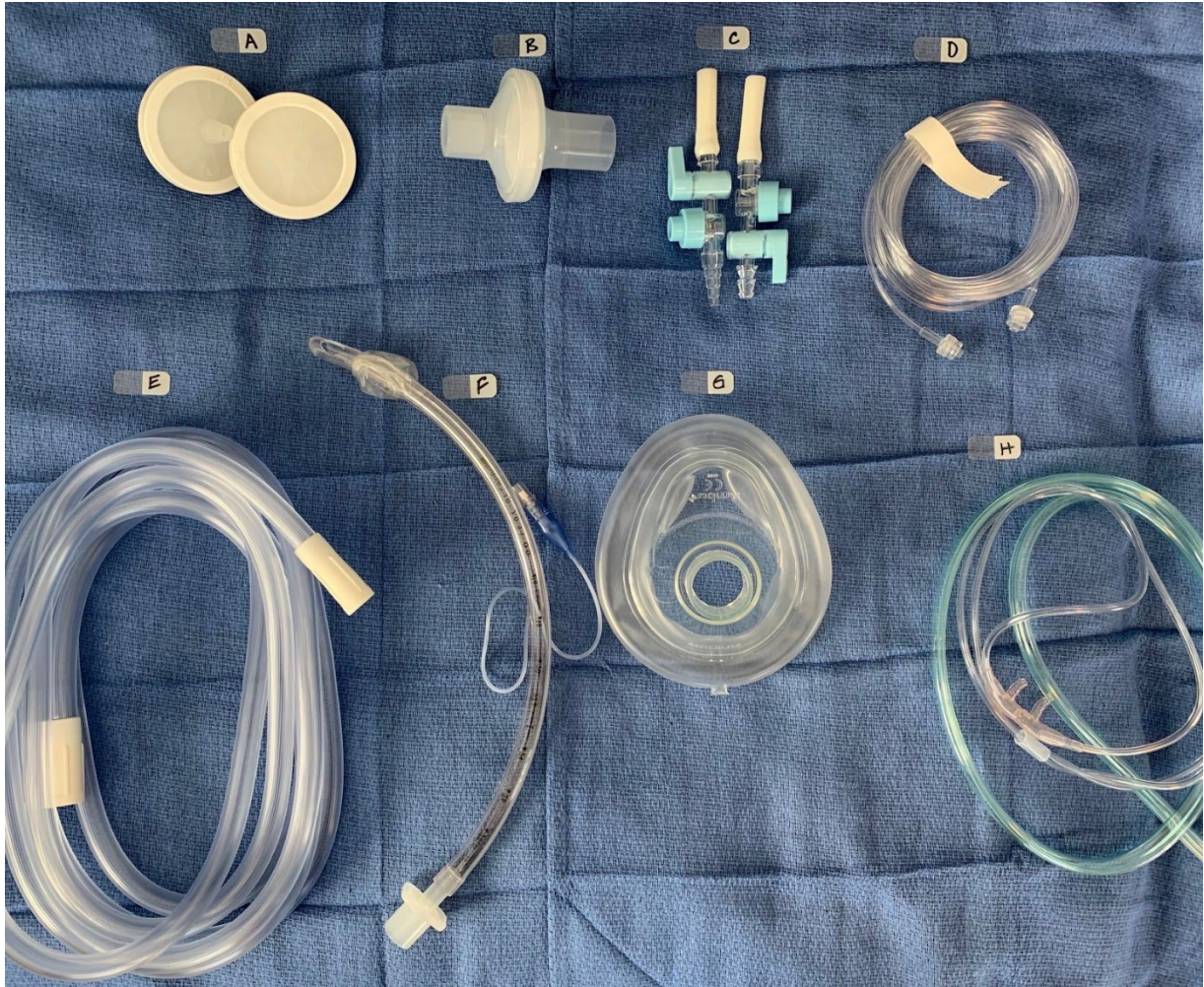
- Open the provided kit of accessories in the Airway Dome package that includes an (A) anesthesia circuit tube, (B) end-tidal CO₂ extension monitor line, (C) O₂ extension line for nasal cannulas and O₂ mask, and (D) “Y” suction connector (x2).



- Unfold the Airway Dome and connect the provided kit of accessories to the connection ports inside the Airway Dome.



- The hospital (or healthcare facility) supplied items include but are not limited to skin-safe adhesive tape, portable or wall-mounted vacuum pump with in-line high-efficiency particulate air (HEPA) filter, portable or wall-mounted oxygen, ventilator or bag valve mask. Hospital disposable items include: (A) in-line suction HEPA filter, (B) anesthesia circuit viral filter, (C) in-line suction on/off valve, (D) end-tidal CO₂ line, (E) suction tubing, (F) endotracheal tube, (G) O₂ mask, and a (H) nasal cannula.

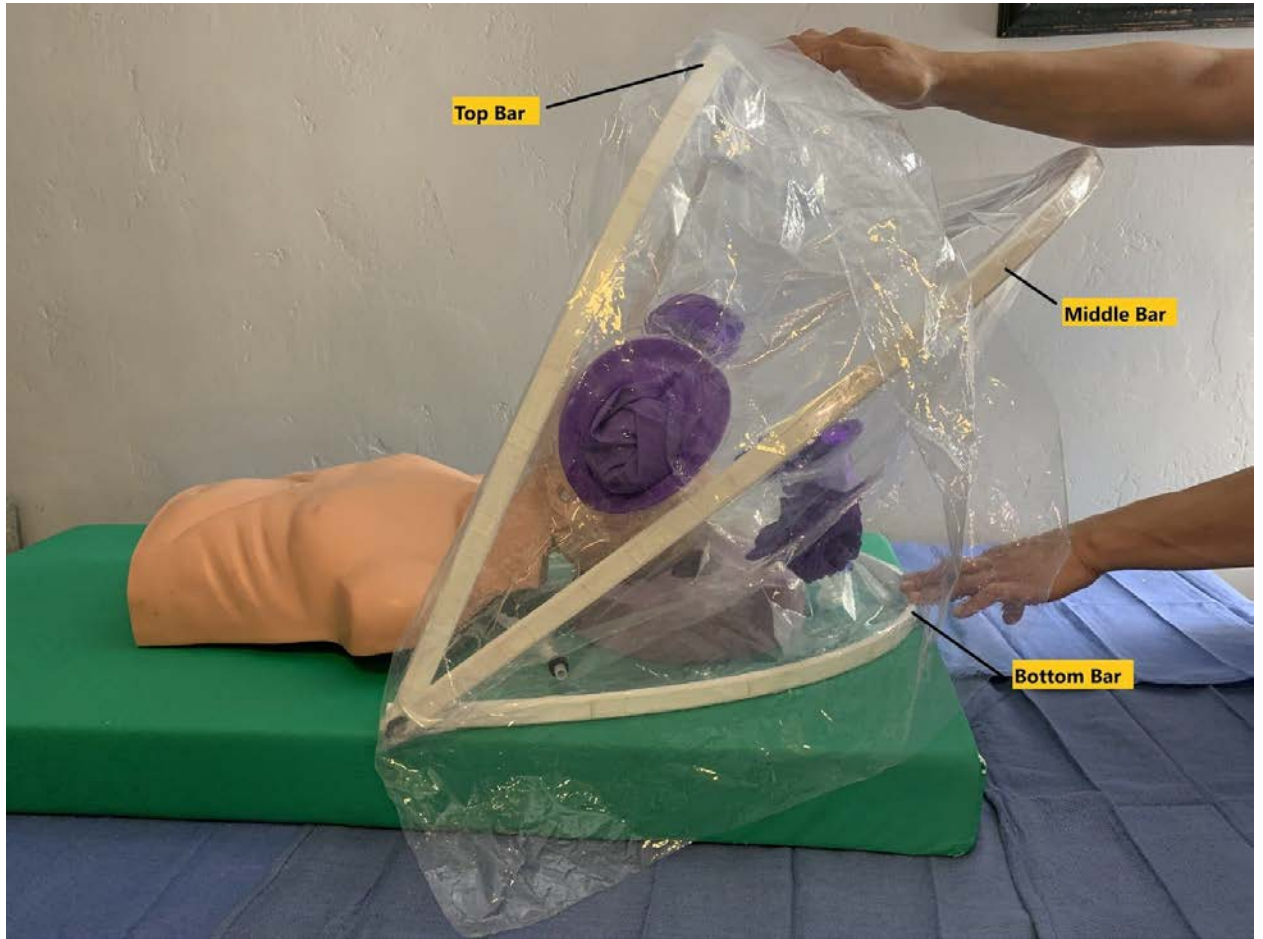


- Fold the Airway Dome back down to allow the patient to lay on the Airway Dome. Place the dome edge joints by the top of the patient's shoulder during the positioning of the patient on the bed. Ensure there is a flat plastic sheet of the dome underneath the head.



- Set any items needed in the Airway Dome for the airway procedure (e.g., suction tube & Yankauer, endo-tracheal tube, laryngoscope, glidescope, etc.) Any items missed or needed later may be added through a “Pass-Through Pouch” on the dome.

- Hold the bottom bar down to the bed while lifting the top bar over the patient's head until the dome is taut.

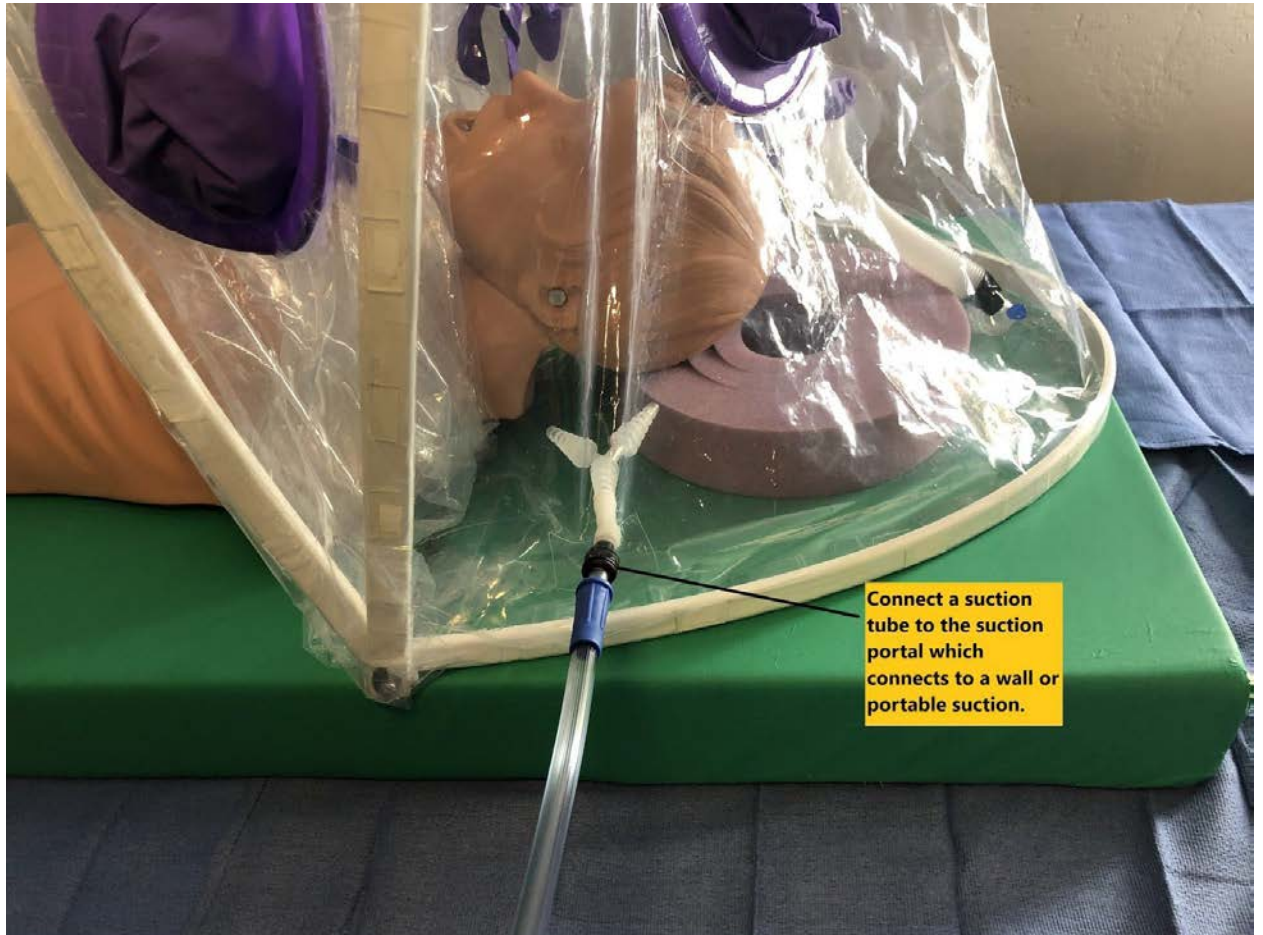


- Pull the folded clear drape down from the top of the Airway Dome to the patient's chest. Make sure the drape has no creases in order to provide a secured barrier. Tuck any remaining drape that is loose under the patient for a more secured seal. Use skin safe adhesive tape (provided by hospital facility) to secure the drape on the patient's chest.

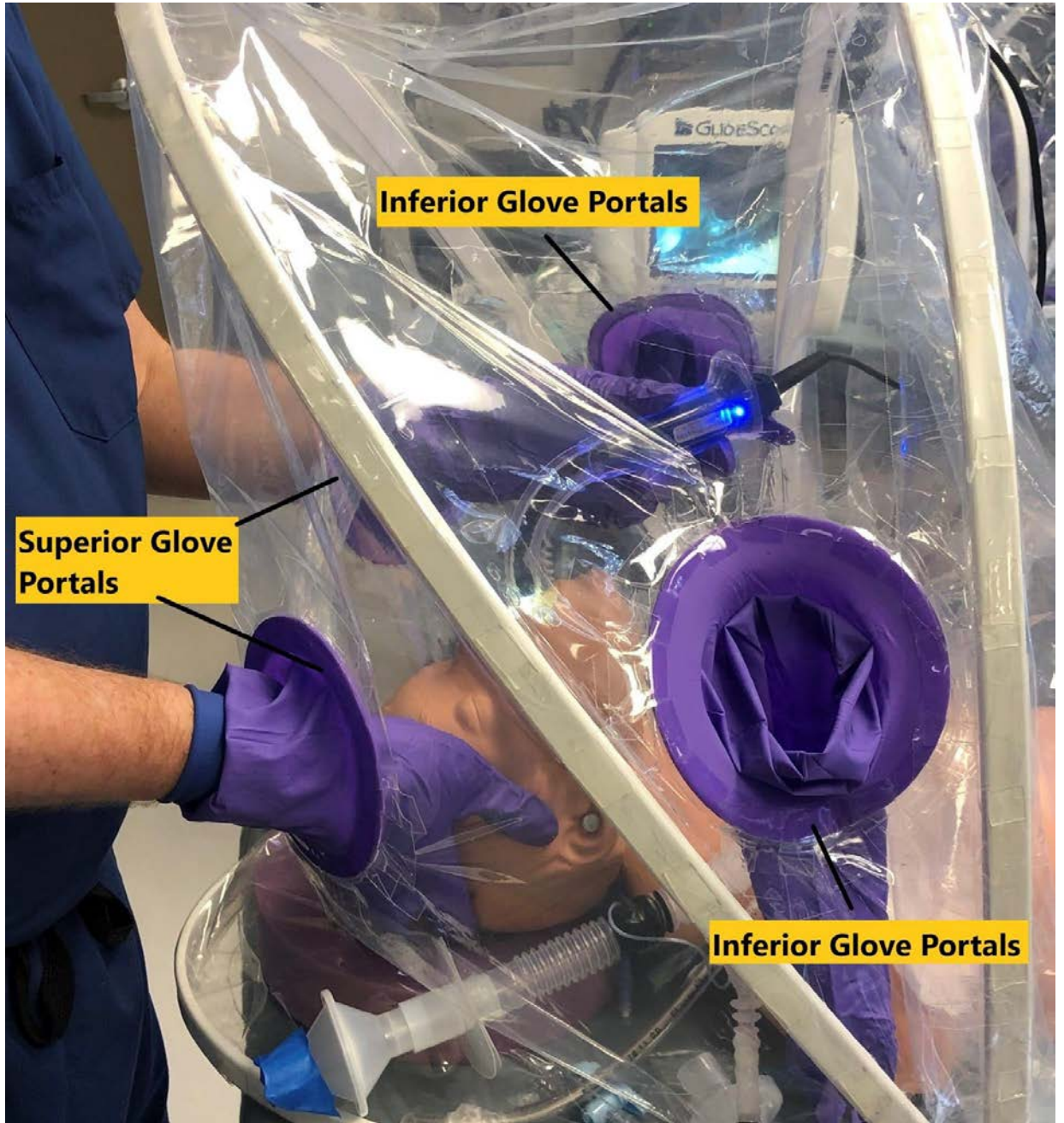


- Walk around the dome again to double check that all loose drapes are securely tucked. This will provide the best negative pressure once suction is turned on.

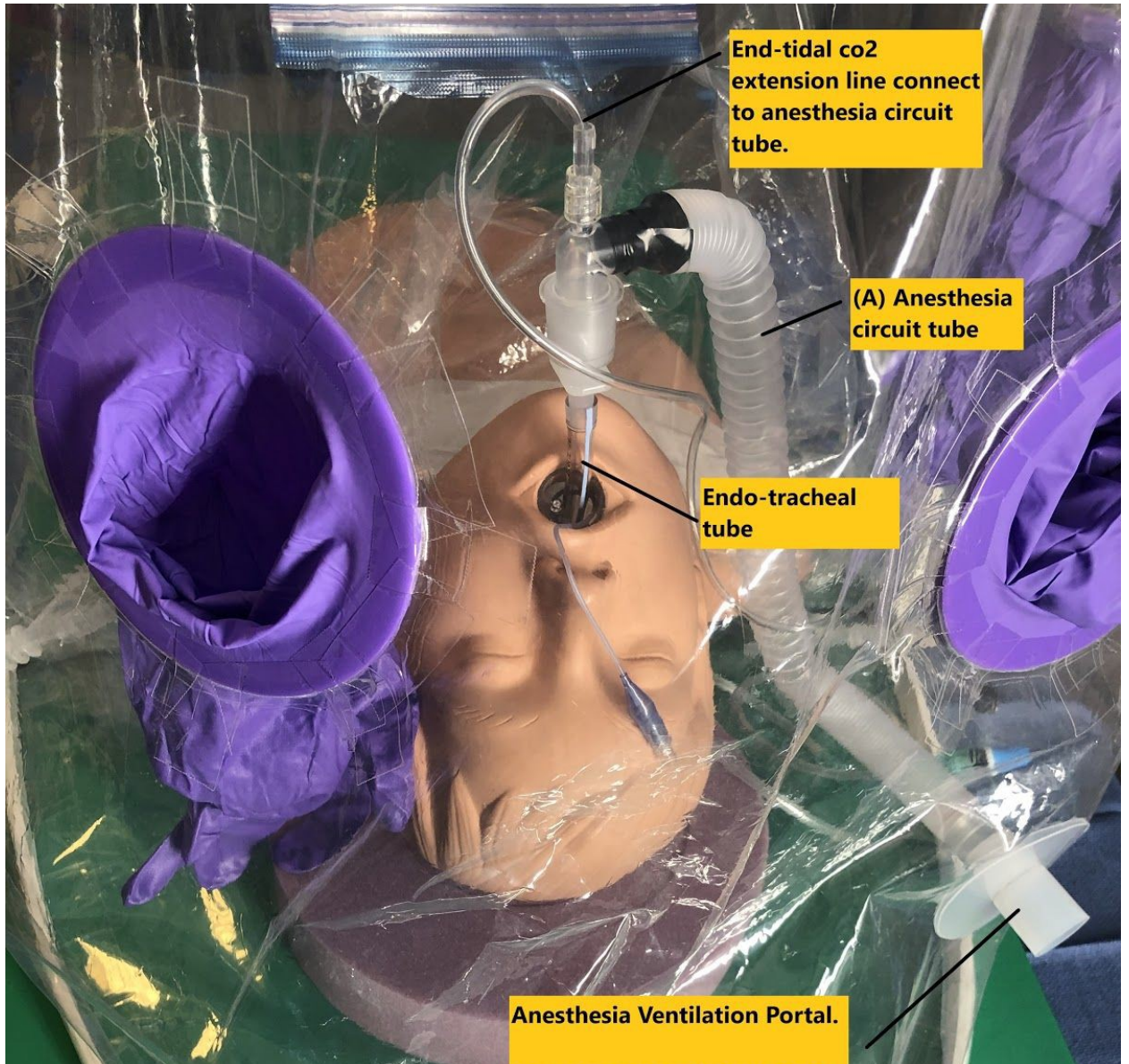
- Connect the suction tubing to the suction portals. Both suction portals can support a Yankauer suction device and a negative pressure environment, which keeps pathogenic biological airborne particulates from leaking out.



- An HCP can access the glove portals superior to the head to perform an airway procedure (e.g., endo-tracheal tube placement or a laryngeal mask airway). Gloves should be worn prior to inserting hands into the glove portals. There are 2 inferior glove portals, one on each side of the dome to allow another person to assist with handling instruments or to provide cricoid pressure.



- Connect the anesthesia circuit tube inside the dome to an endotracheal tube or a laryngeal mask airway to provide O₂ support. The end-tidal CO₂ line should be connected to the endo-tracheal tube or laryngeal airway mask through the end-tidal CO₂ portal to monitor CO₂ levels if the option is available.



- If using a nasal cannula or a simple O₂ face mask, use the available O₂ port on the dome to connect the oxygen source to it. Unused ports should be covered with a diaphragm and kept air tight.

Disposal Instructions



The Airway Dome is a one-time use device. The device after use is a biohazard with proper disposal of the Airway Dome as per the facility standard procedure.

Please instruct all personnel involved in breakdown and disposal of the Airway Dome to be dressed in full PPE.