

## **Instructions for Healthcare Provider (HCP): Use of the 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. HCP should follow these instructions, as well as procedures at their healthcare facility to use the Airway Dome. 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), SpO<sub>2</sub>% (oxygen saturation), End tidal carbon dioxide (EtCO<sub>2</sub>) 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.



**The instructions below are to assist in using the 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 appropriate 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 be used with medical air flow and suction**

both on and working, under direct observation, and with end-tidal CO<sub>2</sub> monitoring if available. If end-tidal CO<sub>2</sub> 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.

- 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 on supplemental oxygen. Patients must have continuous monitoring of pulse oxygen saturation (Sp-O<sub>2</sub>), vital signs, EKG, and End-tidal CO<sub>2</sub> 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 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.

#### **Emergency Removal Instructions**

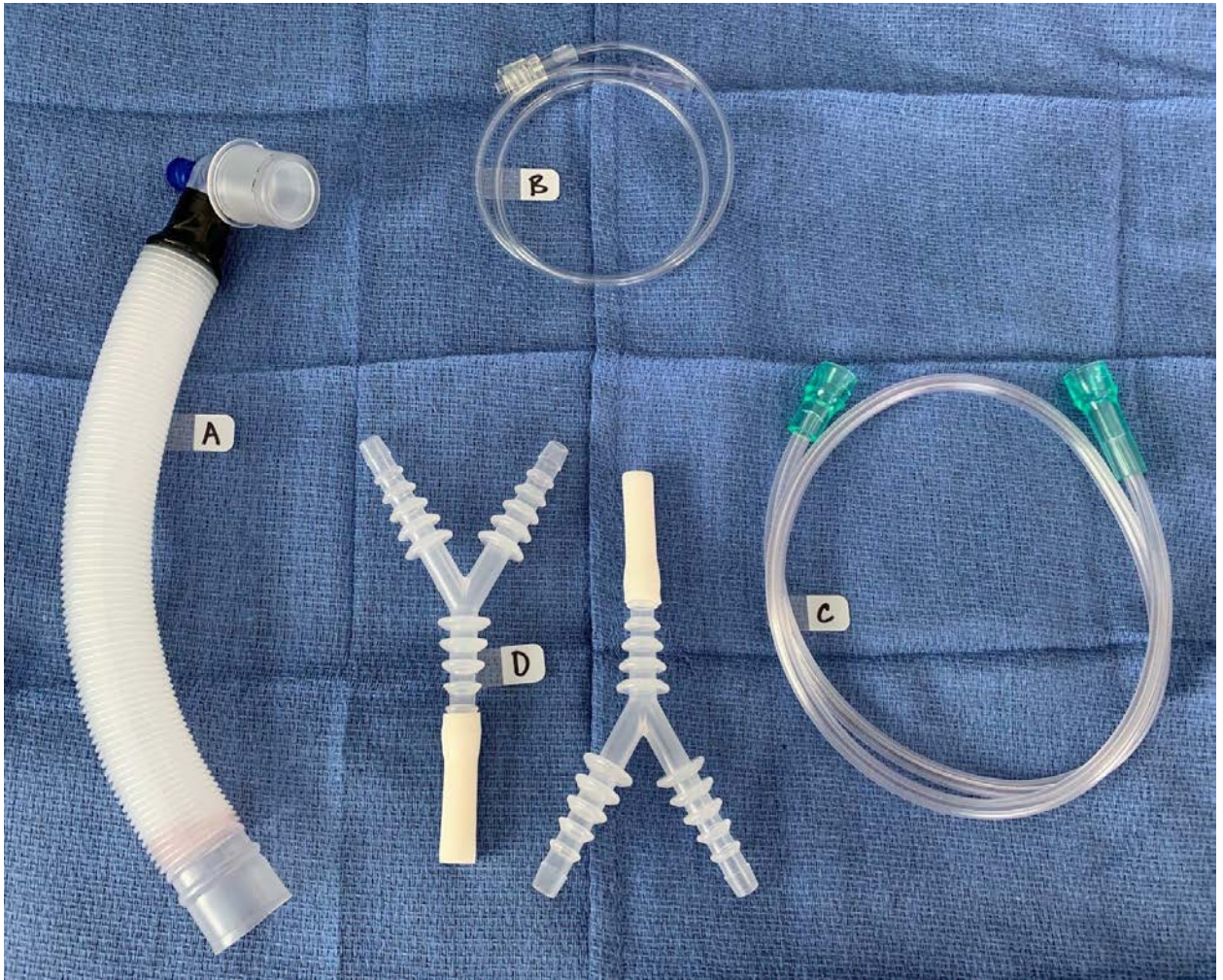
- 1. If the bag needs to be opened emergently, the operator and nearby personnel should be wearing appropriate maximal PPE including an appropriately fitting N95 respirator in case of pathogenic biological airborne particulate exposure or leave the area immediately if without appropriate PPE.***
- 2. Once appropriate PPE by operator and surrounding personnel is confirmed, the medical grade tape (skin safe adhesive tape) can be removed from the patient's chest, and the Airway Dome can be retracted down toward the head of the patient.***

#### **Airway Dome Instructions for Use**

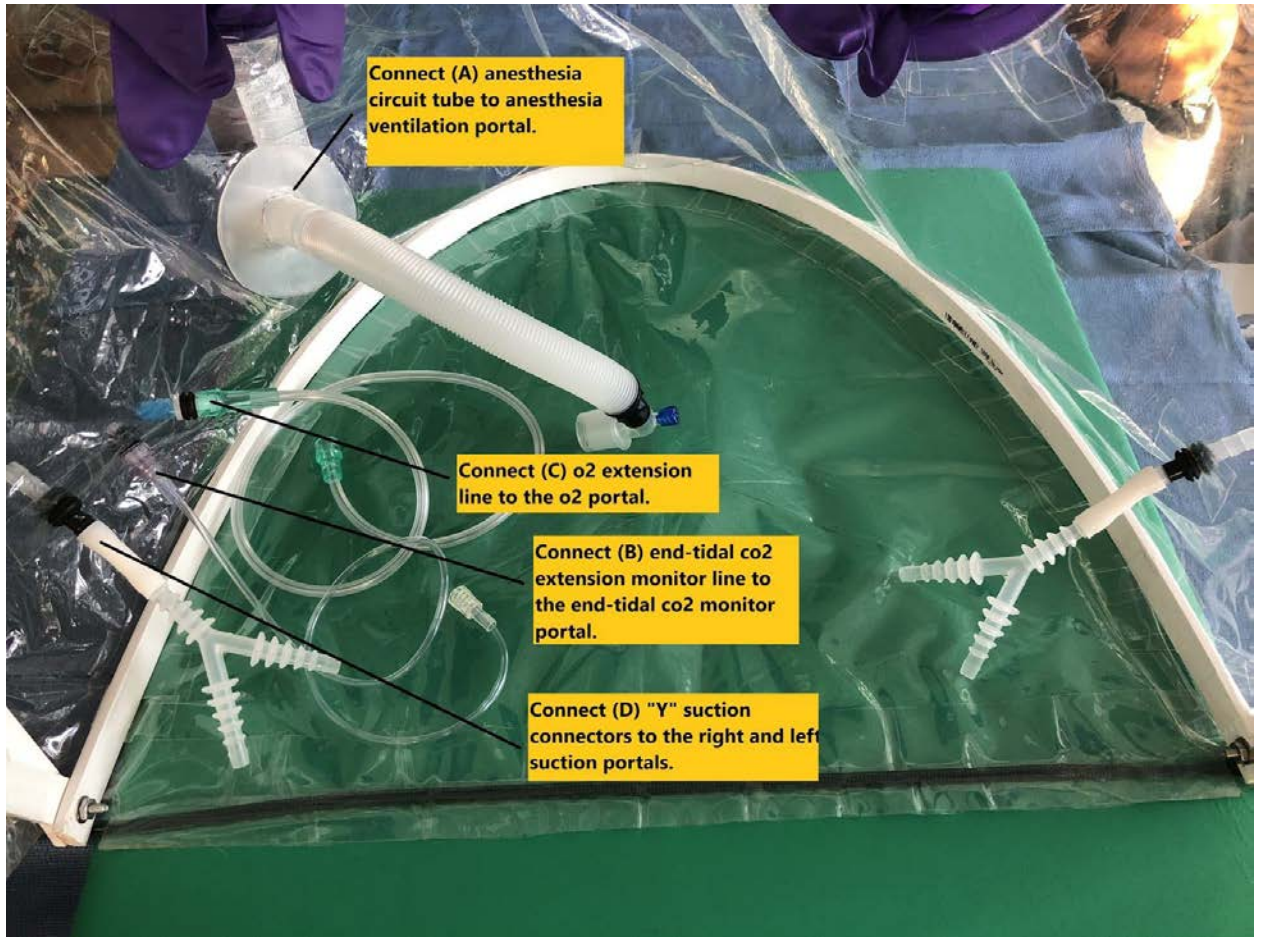
- Open and remove the Airway Dome from the package and place at the head of the bed.



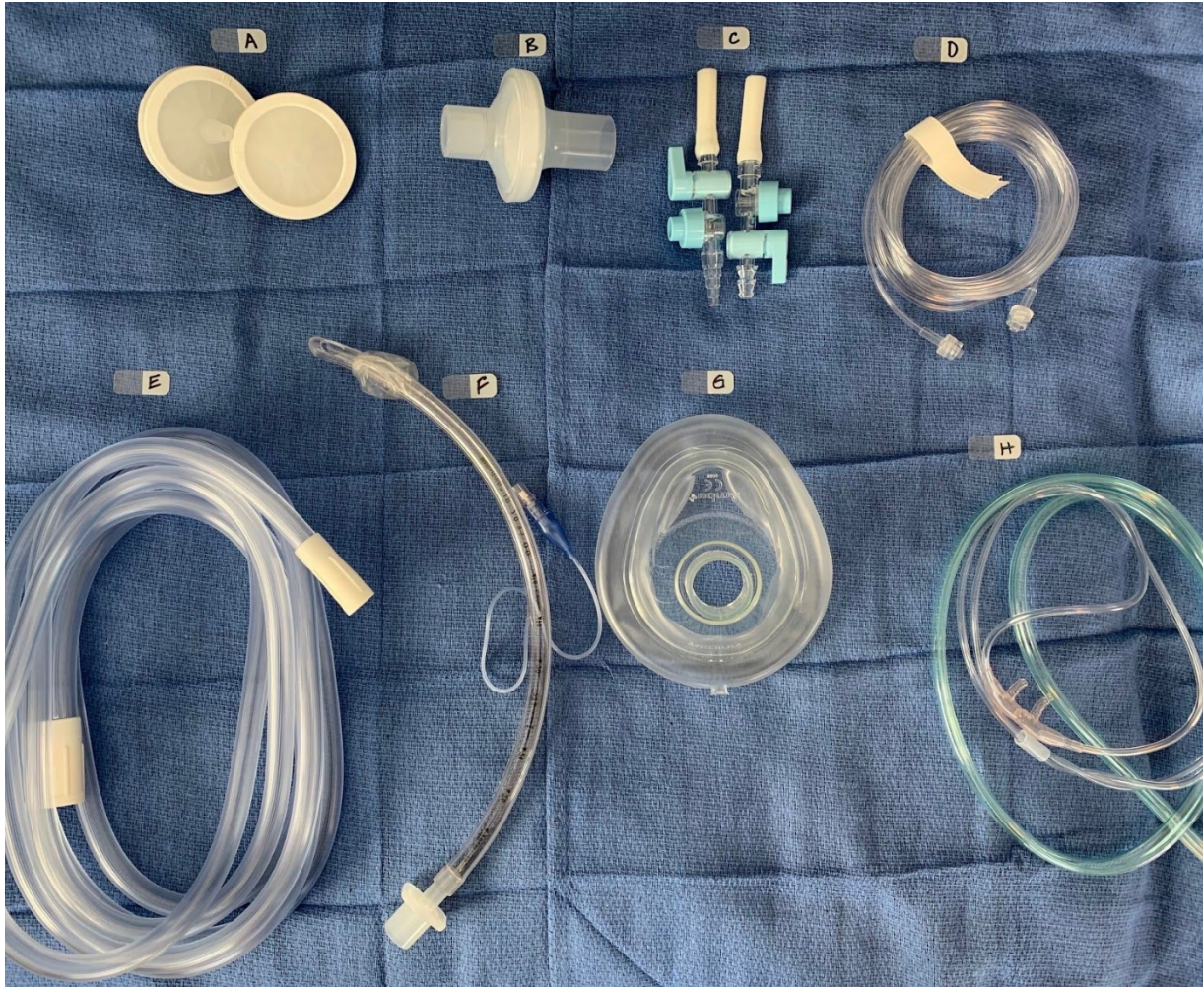
- Open the provided kit of accessories in the Airway Dome package that includes an (A) anesthesia circuit tube, (B) end-tidal CO<sub>2</sub> extension monitor line, (C) O<sub>2</sub> extension line for nasal cannulas and O<sub>2</sub> mask, and (D) “Y” suction connector (x2).



- 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 CO<sub>2</sub> line, (E) suction tubing, (F) endo-tracheal tube, (G) O<sub>2</sub> mask, and a (H) nasal cannula.



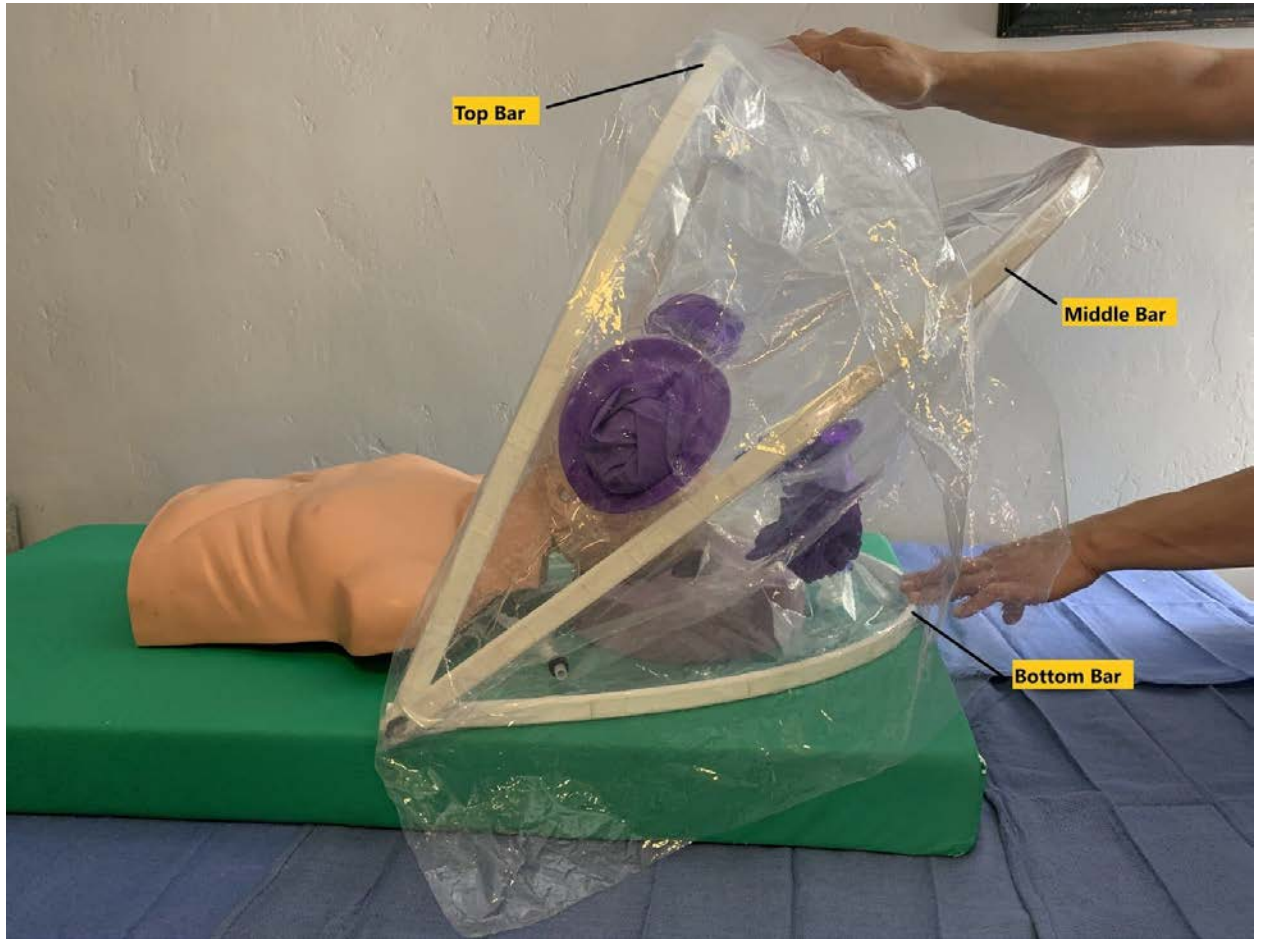
- Fold the Airway Dome back down to allow the patient to lay on the Airway Dome. Place the dome edge joints by the top of the patient's shoulder during the positioning of the patient on the bed. Ensure there is a flat plastic sheet of the dome underneath the



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.

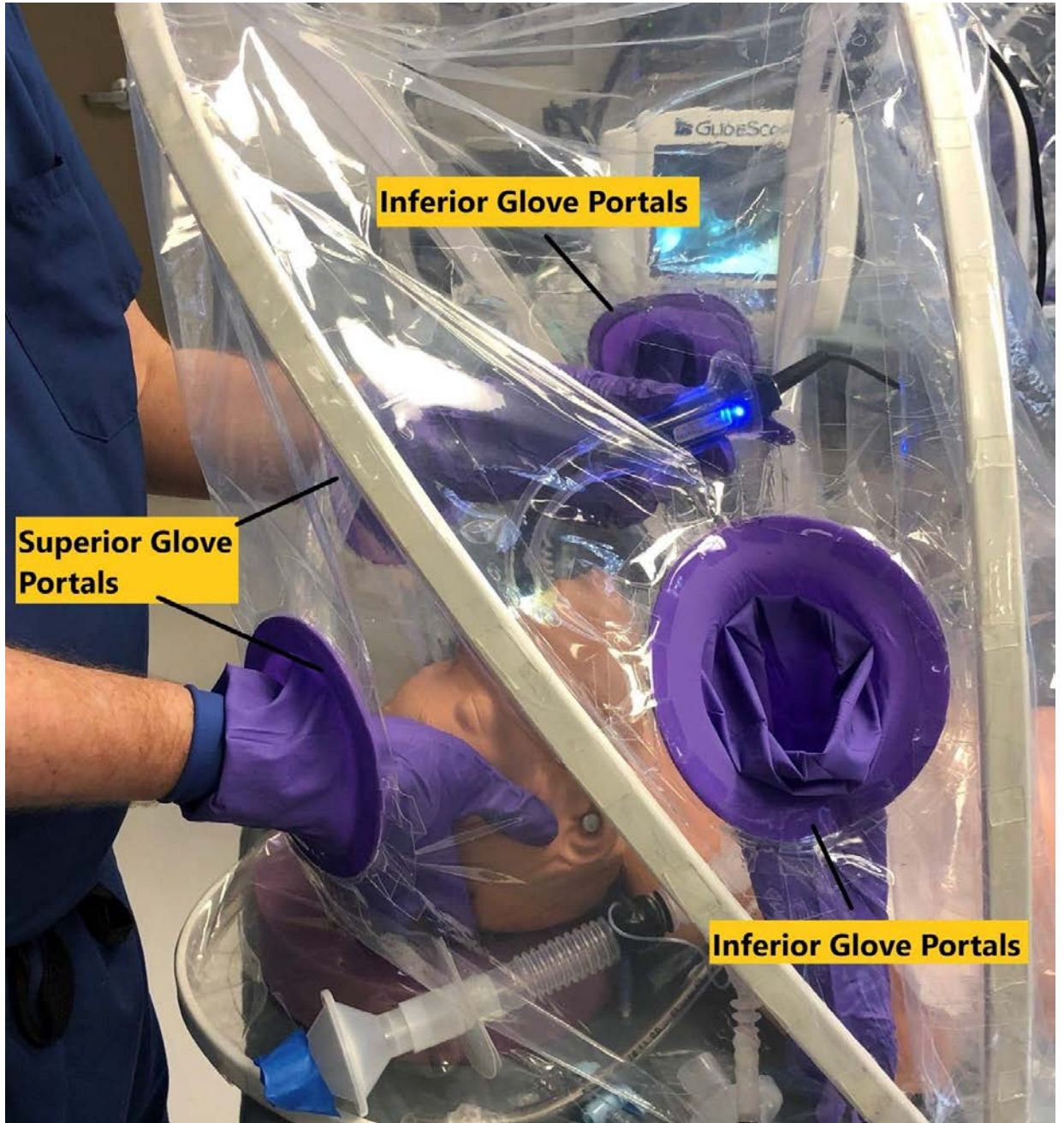


- Walk around the dome again to double check that all loose drapes are securely tucked. This will provide the best negative pressure once suction is turned on.

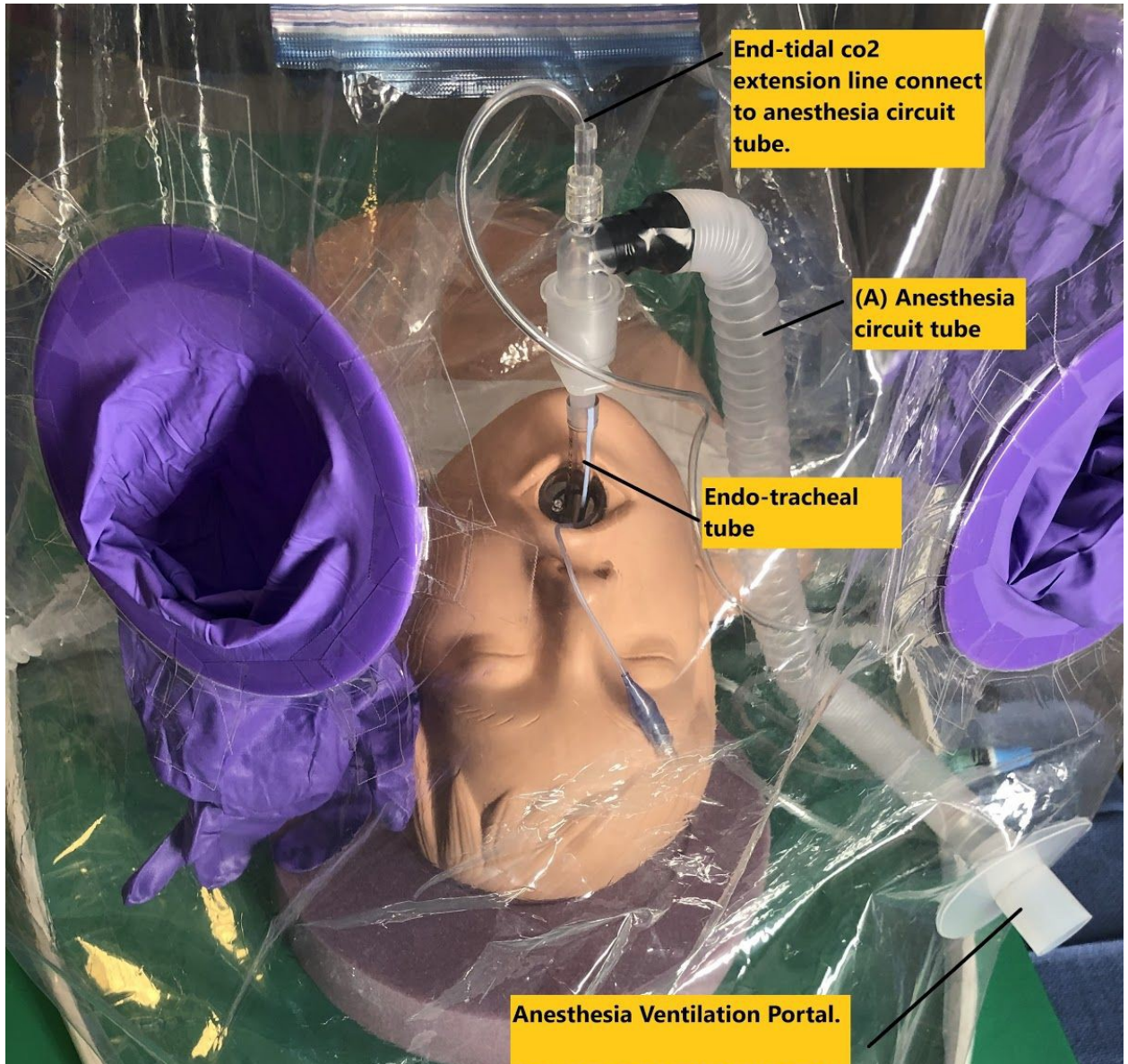
- Connect the suction tubing to the suction portals. Both suction portals can support a Yankauer and a negative pressure environment, which keeps pathogenic biological airborne particulates from leaking out.



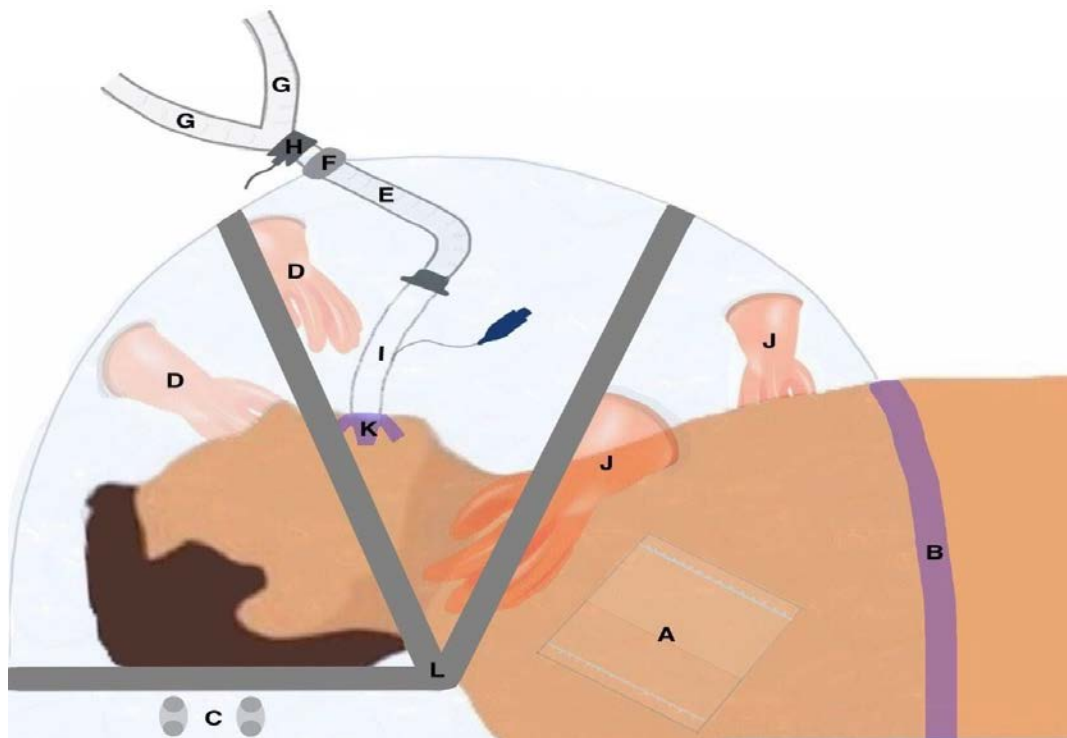
- An HCP can access the glove portals superior to the head to perform an airway procedure (e.g., endo-tracheal tube placement or a laryngeal mask airway). Gloves should be worn prior to inserting hands into the glove portals. There are 2 inferior glove portals, one on each side of the dome to allow another 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 O<sub>2</sub> support. The end-tidal CO<sub>2</sub> line should be connected to the endo-tracheal tube or laryngeal airway mask through the end-tidal CO<sub>2</sub> portal to monitor CO<sub>2</sub> levels if the option is available.



- If using a nasal cannula or a simple O<sub>2</sub> face mask, use the available O<sub>2</sub> port on the dome to connect the oxygen source to it. Unused ports should be covered with a diaphragm and kept air tight.



### Illustrative clinical scenario sequence:

1. An adult male arrives in the ED with suspected COVID-19 and progressive acute airway distress requiring urgent intubation. Routine principles of airway management should be followed to include PPE equipment of mask, gloves, eye protection, and gown. Consent should be obtained when possible.
2. The airway specialist procures the appropriate standard equipment for intubation and places them in the resealable plastic intubation "Pass-Through Pouch" bag (A) to place inside the Airway Dome. The equipment may include appropriate endotracheal tube or Laryngeal mask Airway (LMA) with one size smaller, tube securement device, syringe to inflate the tube cuff, inline suction, video laryngoscope (Concurrent Media Access Control (CMAC) or Glidescope), nasogastric tube, and non-vented mask.
3. The patient is placed in a supine position with supplemental O<sub>2</sub> and continuous pulse oximetry. The Airway Dome is opened and positioned over the patient's head and neck to the upper thorax. There is a flat plastic sheet of the dome underneath the head.
4. Skin sensitive medical tape (B) is placed along the inferior edges of the dome to seal the dome to the neck, torso.
5. A viral filter is placed on the outside dome suction port (C) as needed and linked to suction to provide negative pressure.
6. Using the superior glove access portals (D), the inflated mask is placed over the nose and mouth for pre-oxygenation. Mask is linked to the multi-adaptor circuit (E) inside the dome. A second viral filter (F) may be placed on the

outside dome portal for the airway followed by the anesthesia airway ventilator circuitry (G).

7. An end tidal CO<sub>2</sub> adaptor (H) may be placed between the ventilator circuit and viral filter. This configuration protects the end tidal CO<sub>2</sub> sampling line. All connections are secured.
8. Rapid sequence anesthesia induction is recommended. Medical paralysis of patient is done prior to intubation with the endotracheal tube (I) to avoid coughing and subsequent aerosolization of particles.
9. Intubate patient with video laryngoscope (or regular laryngoscope if desired) through superior glove access portal (D) utilizing assistant through the inferior glove access portal (J) for cricoid pressure, removing tube stylet, inflating tube cuff, securing tube tape (K), and in-line suction as needed.
10. Ensure capnography (H) confirms endotracheal placement in trachea and continue ventilating.
11. Post-procedure, transfer patient to bed for transport to ICU with ventilation via BVM. The ventilation bag is outside the dome. Once in ICU, patient tubing outside the dome may be connected to a ventilator. Planned extubation occurs with the dome in place. Supplemental oxygen can then be delivered through a simple face mask or nasal cannula connected through the dome oxygen valve. CO<sub>2</sub> is scavenged through the viral filter by negative pressure created by the suction. As a safety precaution, all patients in the dome without a secure airway should have supplemental oxygen via nasal cannula or simple face mask. This will further prevent hypercarbia while the patient is in the dome. The dome is disposed of as other PPE when no longer needed.

## **Disposal Instructions**

PPE should be donned during the disposal of the Airway Dome following the facility's policy and protocol for disposal of biohazardous waste. The Airway Dome is a single patient use item and is not to be reused under any circumstances.