Apollo Medical Solutions

APOLLO 4 Patient Isolation Hood

Instructions, Labels, and Standard Operating Procedure

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare provider.

REPORTING LANGUAGE

NOT INTENDED TO REPLACE PPE

SINGLE PATIENT USE

WARNING

Patient Unattended Hazard.

Leaving patient unattended can cause harm. A qualified care team member must accompany patient at all times.

WARNING

Suffocation Hazard.

Plastic film can be dangerous. To avoid danger of suffocation, keep this film away from the mouth of the patient.

WARNING

Fire Risk. **OXYGEN RICH ENVIRONMENT**

NO combusitbles inside hood while in use, including hand sanitizer or cleaning solutions.

NO ignition sources inside hood, including any electronics, lasers, heat, or light sources.

Apollo 4

Negative Pressure Isolation Hood

PRIOR TO USE: LABELS AND PRECAUTIONS

PRODUCT DESCRIPTION:

COMPONENT LIST:

INDICATIONS FOR USE:

INTENDED USE:

THIS PRODUCT IS AUTHORIZED FOR USE BY FDA UNDER AN EMERGENCY USE AUTHORIZATION (EUA) PURSUANT TO SECTION 564(b)(1)(C) OF THE FEDERAL FOOD DRUG AND COSMETIC ACT

THIS PRODUCT IS NOT AN FDA APPROVED MEDICAL DEVICE, USE OF THIS DEVICE IS AUTHORIZED BY THE FDA FOR THE DURATION OF THE EUA AND SHOULD NOT BE USED AFTER THE EUA HAS BEEN CONCLUDED, TERMINATED, OR REVOKED BY THE FDA.

PRIOR TO USE: Health care provider should assess patient for respiratory status and difficult airway prior to use of this device.

PRECAUTIONS:
+If device impedes care of or communication with patient it should be removed immediately following instructions in "Removal of Device" section of this page, below.
+Normal PPE should be used in conjunction with this device. Device not intended to replace PPE.
+The Benefits/Risks of using a protective barrier enclosure device for airway management in certain populations should be predetermined by the HCP. These populations include but are not limited to:

- -Patients requiring emergency endotracheal intubation who have severe respiratory compromise
- -Patients with an anticipated or known history of difficult airway
- -Patients who are morbidly obese
- -Pregnant women in the 2nd or 3rd trimester
- -Individuals with severe claustrophobia and/or confined space anxiety
- -Individuals with certain communication disorders
- -Patients with other anatomical abnormalities
- -Patients with decreased neck mobility due to arthritis or other causes

SET UP OF DEVICE: See next page for setup instructions.

USAGE: See SOP for use instructions. This device intended for use on one patient. Dispose after use. Not intended for re-use.

BODY CONTACTING MATERIALS:
+Thermoplastic Polyurethane (TPU)
+ Polyethylene Terephthalate Glycol-modified (PETG)
+ Low Density Polyethylene (LDPE)

CLEANING: If cleaning unit before use is required for any reason an isopropanol based cleaner is recommended as other cleaning agents may damage TPU or other plastics on device. This product is intended for use on a single patient and should not be reused.

REMOVAL OF DEVICE: If device impedes care of or communication with patient it should be removed immediately. To remove follow these steps:

1) Unhook cords from both sides of the device (four hooks total)
2) Lift front drape to avoid covering patient's face
3) Slide device out from beneath patients head, gently lifting patients head if necessary.

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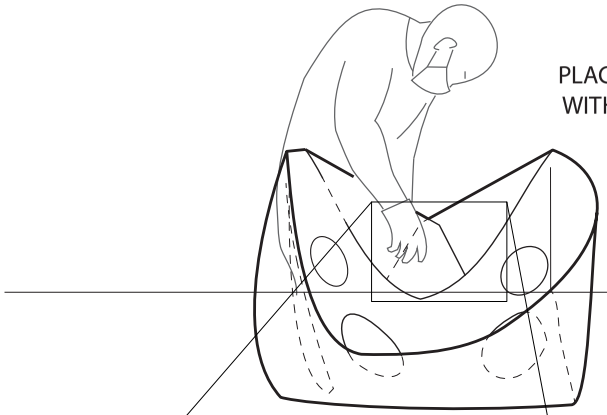
Negative Pressure Isolation Hood

SETUP INSTRUCTIONS

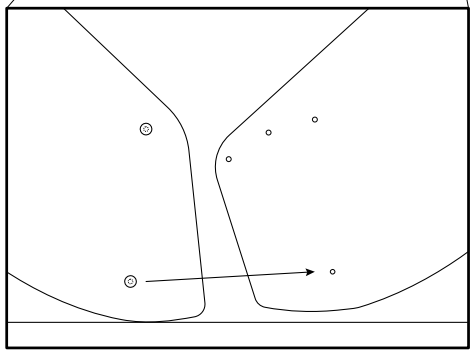
1

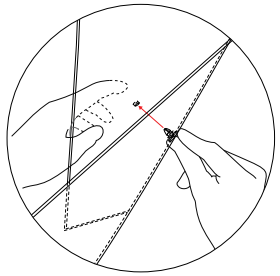
PLACE HOOD ON CLEAN SURFACE
WITH HOOD OPENING FACING UP



2

INSERT BOTTOMMOST RIVET



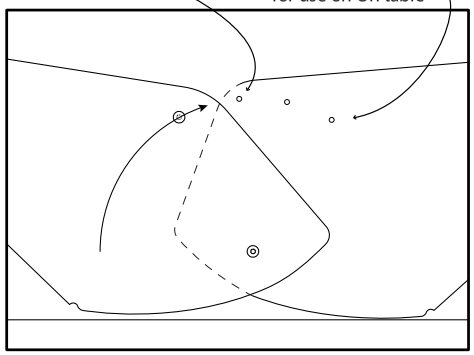


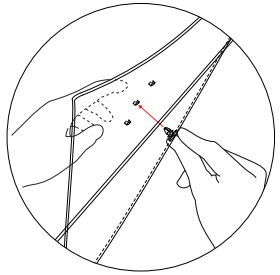
3

ROTATE UPPER RIVET TO
SELECT DESIRED HOOD WIDTH

wider/shorter

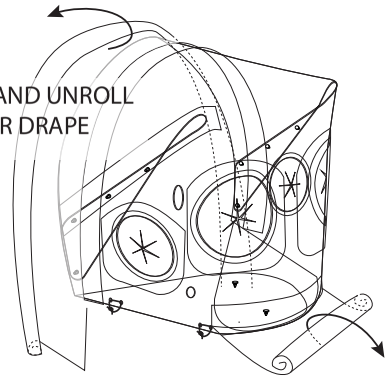
taller / narrower
for use on OR table





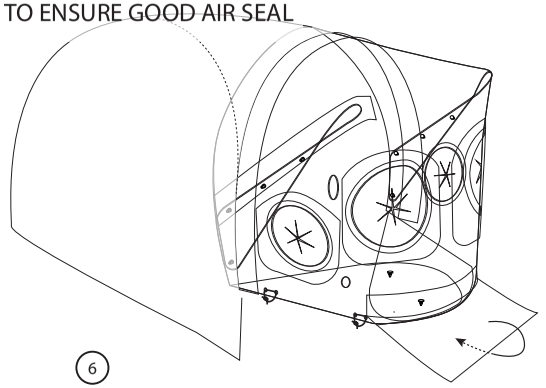
4

REMOVE BLUE TAPE AND UNROLL
FRONT AND REAR DRAPE



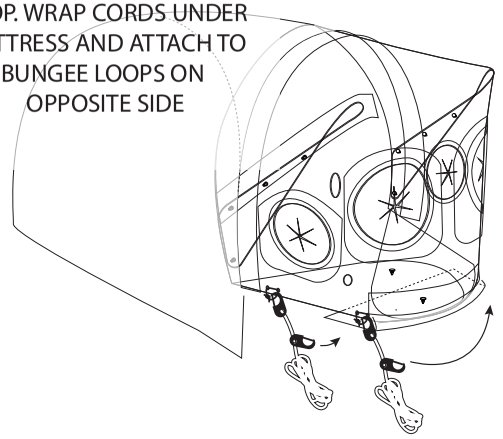
5

TUCK REAR DRAPE UNDERNEATH
HOOD TO ENSURE GOOD AIR SEAL



6

ATTACH CORD CLIPS TO BUNGEE
LOOP. WRAP CORDS UNDER
MATTRESS AND ATTACH TO
BUNGEE LOOPS ON
OPPOSITE SIDE



Apollo Medical Solutions, 2020
46 Cottage Street, Watertown, MA, 02472

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STANDARD OPERATING PROCEDURE

1. SETUP and USE

• Place patient in hood

• Place procedure instruments in hood (e.g., intubating equipment, ventilator tubing, etc.) through the FRONT of the hood under drape- do NOT attempt to place them though the arm ports as this can restrict movement needed for intubation. At no time should indwelling patient lines be put through arm ports as this could hinder emergency removal safely.

• Lower drape to enclose space, tuck drape in around patient's body, place blanket over chest and drape edge to help seal chamber as much as possible. Some minor entrainment of room air is expected.

• Turn on suction prior to beginning aerosolizing procedure (see table below for which suction is acceptable)

• Perform procedure- (e.g. intubation, initiate CPAP, etc.). Emergency note: Health Care Provider (HCP) can pull drape up or remove entire hood immediately in case of hood impairs care or communication. Remember, the hood is not intended to replace proper PPE.

• For temporary aerosolizing procedures (intubation, extubation, etc.) leave drape down for 12 minutes (single wall suction line) or 2 minutes (DESCRIPTION OF EVACUATOR HERE), see chart below.

• If aerosolizing procedure is ongoing (eg, CPAP, HFNC, etc) then EVACUATOR suction must be used continuously, other than during brief transport. If suction is off for any reason, or drape must be raised, aerosol protection will decrease significantly. In this scenario HCP may consider non-aerosolizing oxygen source if clinically acceptable option is available.

• Disposal: ensure hood is NOT returned to stock rooms for re-use. Single patient use only. Apollo hood and all parts are fully disposable. If hood is temporarily removed from patient, it is to be placed in a non-contact area, off the floor and within the patient room while awaiting re-application for use on the same patient at a later time.

Suggested suction choice (all wall suction requires a HEPA filter- Buffalo filter is built in)

	Wall Suction at Max (40L/min)	Buffalo suction set at 80% power	Comments
Intubation / extubation	●	●	Buffalo suction preferred
TEE or EGD (intubated)	●	●	Buffalo suction preferred
Nebulizer treatment	●	●	Buffalo suction preferred
Bronchoscopy / BAL	●	●	Buffalo suction preferred
CPAP/BIPAP		●	Buffalo suction 80% required
HFNC		●	Buffalo suction 80% required