Negative Pressure SteriDome (NPS): Rx Only

Instructions for Healthcare Facilities and Providers

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the Negative Pressure SteriDome (NPS), for use by healthcare providers (HCP) as a single-use 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 (e.g., intubation, extubation and suctioning airways), or when performing aerosol-generating 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/bilevel positive airway pressure) mask use, airway suctioning, percussion and postural drainage), or during certain transport of such patients during the COVID-19 pandemic.

It is intended for use by qualified and trained personnel under the direction or supervision of a physician or other certified HCP in professional healthcare settings with appropriate personal protective equipment (PPE). NPS is not a replacement for PPE. NPS is a single use device and should be disposed of after use following the disposal instructions. For all authorized uses, the patient should always have supplemental oxygen during use of NPS.

NPS use should not exceed one hour. All patients should have medical air or oxygen and suction on and working with direct observation of vital signs, body temperature and end-tidal CO_2 ($EtCO_2$) monitoring, if available, when using NPS. Patient transport when using NPS must be within a hospital setting for temporary transfer with direct admission within the hospital with certified HCP attending to the patient at all times. Negative pressure maintenance with adequate airflow must be assured with NPS. Patients must have continuous monitoring of body temperature, pulse oxygen saturation (SpO_2) levels, vital signs, electrocardiogram (EKG), and $EtCO_2$, if available, during transport.

If end-tidal CO_2 monitoring is not available, then the use of the NPS Device is limited to no longer than 30 minutes with medical air flow and suction both on and under direct observation. For all authorized uses, the patient should always have supplemental oxygen during use of the NPS Device. The device is intended for use by qualified and trained HCP under the direction or supervision of a physician or other certified HCP in professional healthcare settings.

NPS has not been FDA-approved or cleared for this use; NPS has been authorized for emergency use by FDA under an EUA. NPS 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 NPS device. HCP should follow these instructions, as well as procedures at their healthcare facility, to use NPS. NPS is an adjunctive protective barrier designed to mitigate risk of COVID-19 exposure to HCP. NPS is not meant to be a stand-alone unit of PPE. NPS 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 NPS, direct observation is required. Inspect all of the NPS components prior to use, to ensure they are working properly. Any signs of degradation or wear and tear of the NPS must promptly be reported to Breegi Scientific, Inc. In such case, the healthcare facility must not use the product on patients and must properly dispose of the NPS Device. Rx Only.

WARNING:

- Use of NPS should not exceed an hour.
- For short use transport of patients not on ventilators, an external suction device, such as a portable vacuum pump with a high-efficiency particulate air (HEPA) filter must be used along with patient oxygen supply. Patients must have continuous monitoring of body temperature, SpO_2 levels, vital signs, electrocardiogram (EKG), and $EtCO_2$, if available, during transport.
- Flammability of NPS has not been tested. No interventions that could create a spark or be a flammable source should be used within NPS.
- The allergenicity of NPS has not been tested. Device materials may cause allergic reaction.
- Remove NPS and use standard of care if there is difficulty visualizing or identifying anatomical landmarks or inability to intubate after the first try.
- Remove NPS if it impedes ability to care for a patient, communicate with a patient, or perform medical procedure on a patient.
- Prolonged use of NPS may induce hypercarbia in a spontaneously breathing patient.
- NPS should only be used with medical air or oxygen supply for the patient and suction both on and working, under direct observation with monitoring of body temperature, SpO_2 levels, vital signs, EKG, and $EtCO_2$, if available. If end-tidal CO2 monitoring is not available, then the use of the NPS Device is limited to no longer than 30 minutes. with medical air flow and suction both on and under direct observation.
- All patients should be receiving supplemental oxygen when using the NPS.
- Use of NPS for patient transport must only occur within a hospital setting for temporary transfer with direct admission within the hospital with a registered nurse or physician in constant attendance during this time. Maintenance of negative pressure and patient oxygen supply must be assured. Patients must have

continuous monitoring of vital signs, body temperature, Sp-O_2 levels, electrocardiogram (EKG), and $EtCO_2$, if available, during transport.

- NPS is a single-use device and should be disposed of following the disposal instructions after use.

CONTRAINDICATIONS:

NPS is contraindicated for use:

- During surgical procedures
- For emergent endotracheal intubation with severe hypoxemia or respiratory compromise
- On pregnant women in the 2nd or 3rd trimester
- On patients with morbid obesity
- On patients with anticipated or known history of difficult airway
- Individuals with severe claustrophobia and/or confined space anxiety
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- On patients with communication disorders that might interfere with clinical care
- On children under 45 pounds.
- On bariatric patients
- On patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure
- On patients requiring procedures that involve exceeding the maximum direct access slits or holes as stated in this IFU
- In elderly care centers – it is only for use in a hospital environment
- In ambulance transport

NPS Instructions for Assembly, Disassembly, and Disposal

Preparation for use of NPS:

Instructions for assembly are provided in each NPS package.

Following the step-by-step instructions for assembly will yield a fully functional NPS in approximately three minutes. The three-minute setup time should be factored into any procedure time required.

- **Open and remove the NPS components from the package and place at the head of the patient's bed.**

  The dome has three components for assembly:
  (i) Enclosure
  (ii) Frame rods
  (iii) Hub

Open the provided kit of accessories in the NPS package that includes:

(iv) Suction tube connector
(v) In-line bacterial/viral filter
(vi) Suction tubing

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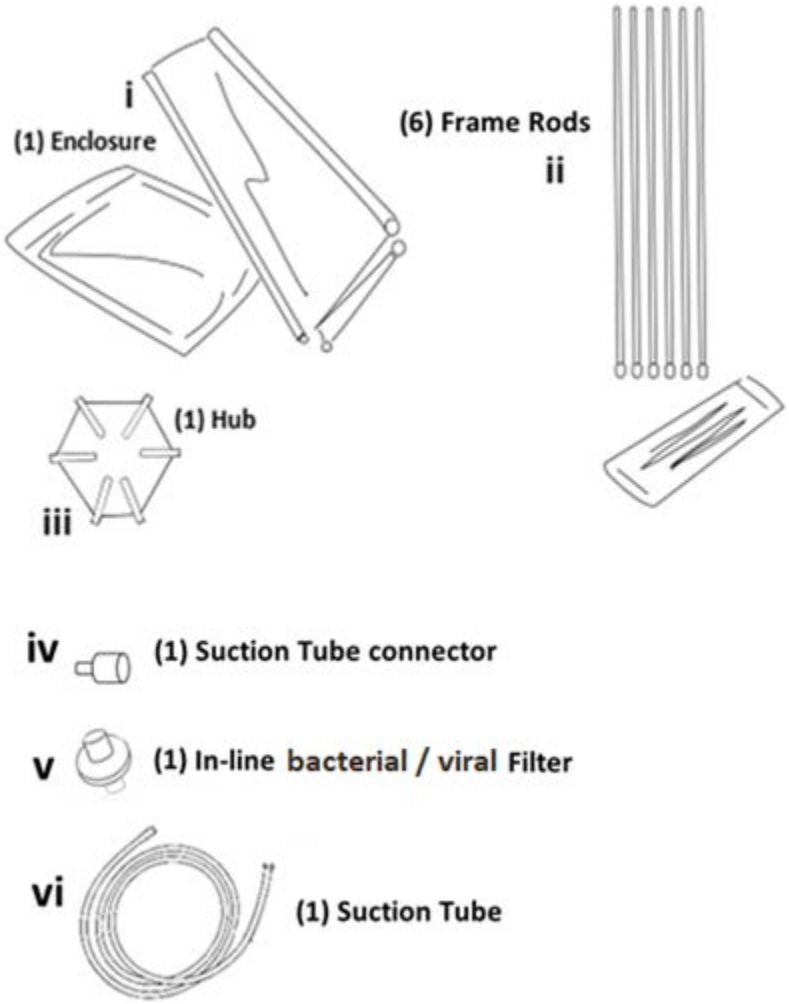


Hospital-supplied components:

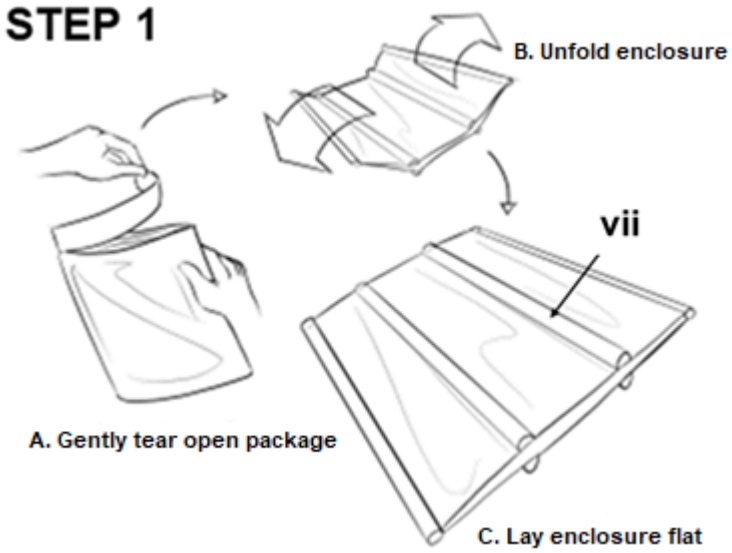
- adhesive tape
- wall-mounted vacuum or portable vacuum pump with an in-line HEPA filter capable of 30 liters per minute flow rate with a pressure regulator reading at least 200 mm Hg
- portable or wall-mounted patient oxygen source
- $EtCO_2$ line
- O_2 mask

- Nasal cannula

NPS Instructions for Assembly:

Step 1:

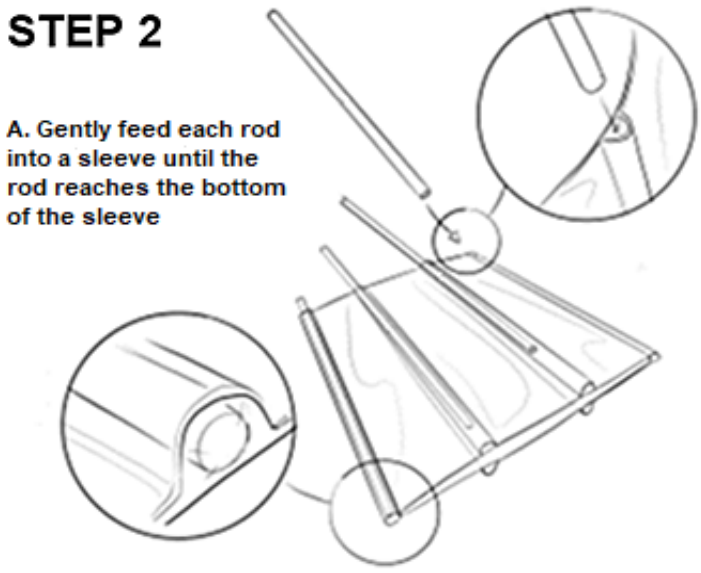
- Open the packaged enclosure (i), unfold, and lay flat.



- Gently loosen and straighten each of the (6) frame sleeves (vii).

Step 2:

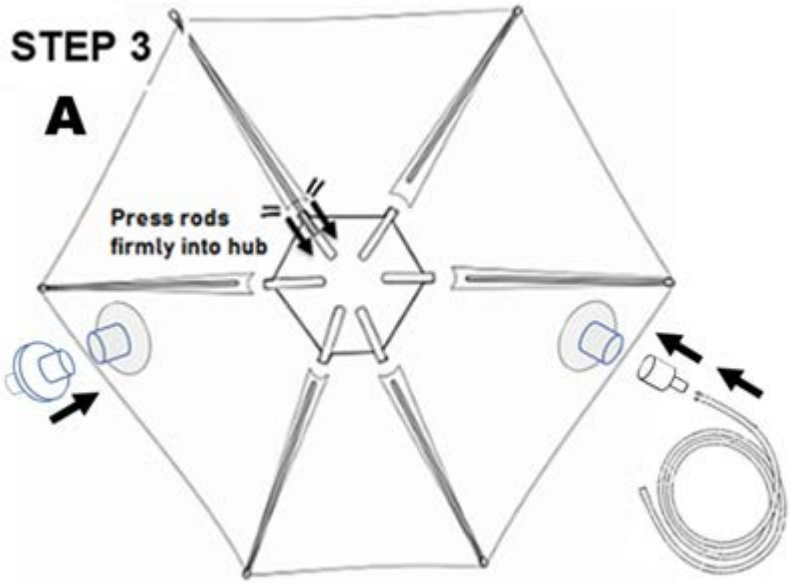
- Gently feed each rod (ii) fully into the top opening of each sleeve (vii).



STEP 3-A:

<u>For use with facility wall-suction capable of at least 30 liters per minute flow rate only</u>:

- Engage securely each rod (ii) into hub (iii) while separating the base of enclosure (i) so that all 6 rods are attached to the hub and secured with the enclosure.
- Connect in-line bacterial/viral filter (v) to one port
- Connect suction tube (vi) to adapter (iv) then to second port and suction source using suction tubing
- Turn on suction source to 200 mm Hg
- Verify that the suction system is equipped with a sufficient filter system to prevent contaminants or discharges from entering into healthcare facility suction discharge system. Pressure regulator capacities may vary. Settings shall be on continuous suction flow. Do not use the suction source in intermittent mode. Typical healthcare facility wall mounted suctions provide up to 200 mmHg. Set wall suction to a high continuous setting.

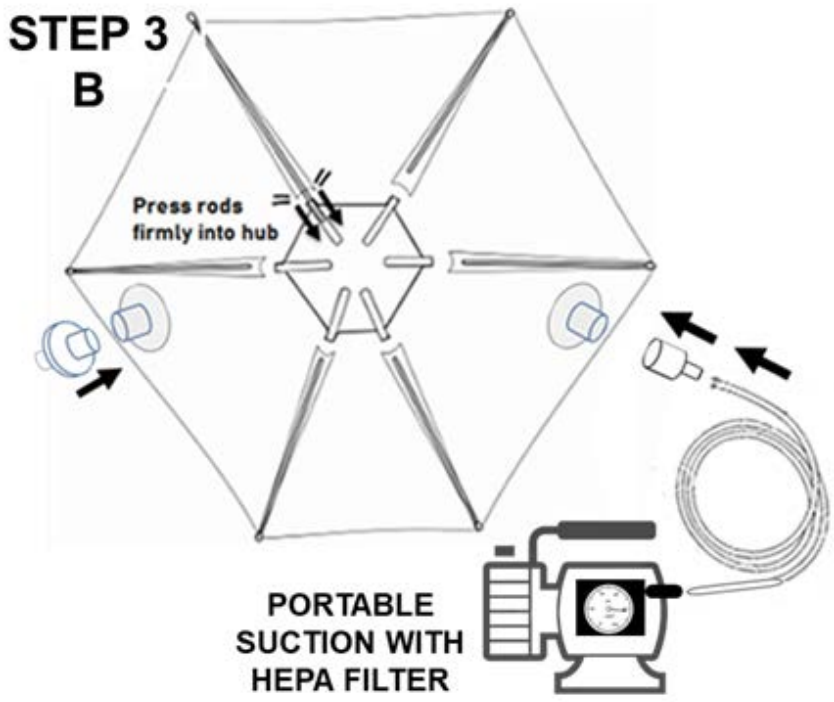


STEP 3-B

<u>For use with portable wall-suction only</u>:

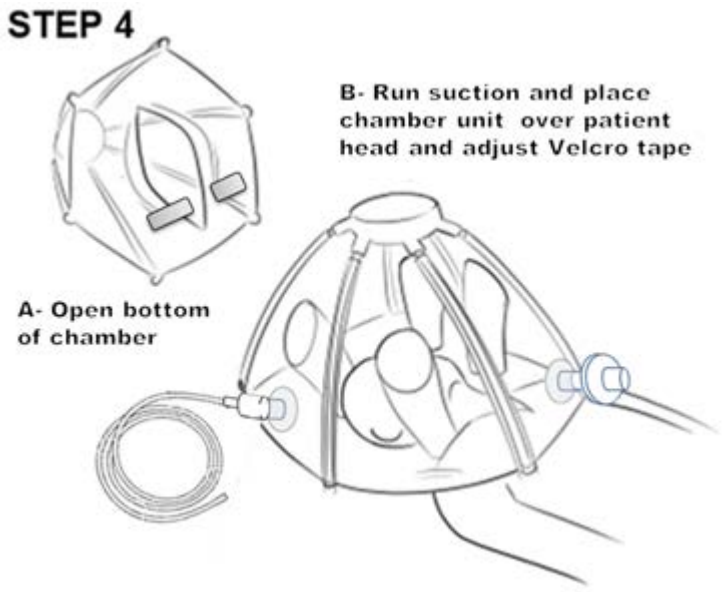
In case of using NPS in transport or the absence of wall suction, a hospital-provided portable suction unit capable of 30 liters per minute flow rate equipped with a standard hospital in-line HEPA filter can be used, with supplemental oxygen for the patient at all times.+

- Engage each rod (ii) securely into hub (iii) while separating the base of enclosure (i) apart all (ii)
- Connect in-line respiratory filter (v) to one port
- Connect one end of the suction tube (vi) to adapter (iv) then to the second port of the base of the enclosure.
- Connect the other end of the suction tube to a portable suction pump with HEPA filter.
- Turn on suction source to maximum setting (200 mm Hg).



STEP 4:

- Ensure patient has supplemental oxygen source. With suction connected and turned on, place NPS onto head of patient via bottom head portal by gently sliding the head portal downward and forward toward the chest.
- Gently secure Velcro tape around neck area.
- As applicable, identify large equipment that will not fit through the bidirectional airlock that will be used to treat the patient.
- Place large equipment through the large access door/portal and close it.



STEP 5:

- **NOTE**: Gloves must be worn prior to inserting hands into the sleeves.
- Wearing gloves, place arms through the arm sleeves to perform the procedure. An HCP can access the sleeve portals superior to the head to perform an airway procedure.

Use:

1. When the patient's head is securely inside, the dome can be rotated for better handling. The patient's head and chest weight should be sufficient to anchor the chamber; however, straps may be used with the bottom loops to anchor the dome to the bed.
2. Pass any tools or medicines you need through the bidirectional airlocks or zipper door (when necessary), using the arm sleeves to reach inside and open the bidirectional airlocks from the inside.

For placing objects in the bidirectional airlocks:

- Slide the locking bag open from the outside
- Place the object inside
- Slide the locking mechanism closed from the outside of the airlock bag
- Reach inside using the arm sleeves to slide the airlock bag open from the inside to ensure optimal containment.

Recommended removal after one use, or on a single patient during a single procedure:

1. While wearing full PPE, remove any accessories from NPS, while keeping suction connected.
2. Undo Velcro strap of the head portal located at the bottom side of the base of NPS to free the patient's neck.
3. Remove NPS gently from the patient's head by sliding the NPS slightly upward and backwards to free the patient's head.
4. Gather the base (bottom layer material of NPS) to occlude the head portal.
5. Use the Velcro strap or facility-provided adhesive tape around the gathered material of the head portal to securely close the opening.
6. Keep suction on and connected for at least **4 minutes.**
7. Carefully remove hub from frame rods.
8. While suction is still on and connected**,** collapse NPS gently.
9. Disconnect suction tube from NPS and apply adhesive tape to close port.
10. Dispose NPS as biohazard waste according to your organizational protocols and adhering to local and national safety guidelines.

Disposal Instructions

NPS is a single use device. The used NPS is a biohazard and requires proper disposal per facility standard procedure. Please instruct all personnel involved in breakdown and disposal of the NPS to be dressed in full PPE.