FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the Negative Pressure SteriDome (NPS) **May 6, 2021**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Negative Pressure SteriDome (NPS). This device is authorized as a single-use extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent healthcare provider (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 aerosol-generating airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

All patients who are treated with NPS should receive the Fact Sheet for Patients: Emergency Use of the Negative Pressure SteriDome (NPS).

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the Center for Disease Control and Prevention (CDC) webpage for the most up to date information.

What do I need to know about the emergency use of NPS?

- NPS is not intended to replace PPE.
- NPS is not intended for use during surgical procedures.
- NPS use cannot exceed one hour.
- NPS is authorized for patient transport within a hospital setting for temporary transfer only for 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 ($EtCO_2$) if available, throughout transport. If end-tidal CO2 monitoring is not available, then the use of the NPS should be limited to no more than 30 minutes with air flow fan on and under direct observation. The patient should always have supplemental oxygen during use of the NPS.
- NPS must be used with facility-provided supplemental oxygen provided via portable or wall-mounted medical air/oxygen source.
- Use continuous pulse oximetry (SpO_2) and End-tidal CO2 ($EtCO_2$) monitoring, if available.
- Ensure the air inlet port has the in-line bacterial/viral filter connected and the outlet port for suction is connected to vacuum source that has either a high-efficiency particulate air (HEPA) filter or the vacuum is part of a healthcare facility wall suction system that evacuates the vacuumed air safely to the environment per institutional building codes and regulations.
- Authorized non-transport use of NPS is only for airway management (e.g., intubation, extubation and suctioning airways), or when performing any aerosol-generating 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].
- Inspect NPS when received for wear/tear of the device or any signs of damage which must be promptly reported to Breegi Scientific. Dispose of such NPS and do not use it on patients.
- NPS is composed of a clear, disposable plastic that provides a portable fiberglass frame-reinforced lightweight chamber (1lb) with built-in airlocks (control ports) for safe delivery of treatments and tools, arm sleeves and ports for air supply/exhaust and fluid delivery.
- NPS can be deployed rapidly and used for patient containment by enclosing the patient's head, while providing access for treatment.

Use appropriate PPE when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*.

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What is the Negative Pressure SteriDome (NPS)?

The NPS device is a single-use layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates. NPS is composed of a clear, disposable plastic that provides a portable fiberglass rod frame-reinforced lightweight chamber (1lb) with a built-in airlock system (control ports) for safe delivery of treatments and tools, arm sleeves and ports for air supply/exhaust and fluid delivery. The negative pressure environment is generated via a portable suction or negative pressure pump equipped with in-line HEPA filter suction devices with an in-line filter or via the healthcare facility wall-mounted suction source.

NPS is comprised of the following components:

- Frame rods, hub, transparent plastic sheeting, access apertures, bidirectional airlocks for inserting additional needed supplies or equipment.

NPS accessories included are: (1) suction hose, (1) hose connector, (1) in-line bacterial/viral filter.

NPS requires the following components which are not included:

- Wall-mounted vacuum or portable vacuum pump with in-line HEPA filter.
- Portable or wall-mounted medical air or oxygen
- $EtCO_2$ line
- O_2 mask
- Nasal cannula
- Adhesive tape

When NPS is used to transport patients on ventilators, all openings should be closed. When NPS is used to transport patients not on ventilators, the NPS maintains negative pressure with portable suction or with negative pressure pumps equipped with HEPA filters. All patients should be on supplemental oxygen. The device is an adjunct to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE.

NPS is a disposable, single use device intended for one patient. Once NPS is no longer needed, dispose NPS as biohazard waste according to your organizational protocols and in adherence with local and national safety guidelines.

When should NPS be used?

The virus that causes COVID-19 is highly contagious and NPS provides an additional layer of protection when exposure to contaminated droplets or aerosolized particles are expected. During use with aerosol generating procedures, the risk of virus transmission is extremely high, and this product can provide an additional layer of protection for the HCP. The patient's respiratory status and airway should be assessed prior to use of NPS.

Preparation for use of NPS:

- ✓ Instructions for assembly are provided in each NPS packaging
- ✓ Following the step-by-step instructions for assembly will yield a fully functional NPS in approximately 3 minutes
- ✓ NPS should completely enclose the intended patient's head, in order to provide additional HCP protection against airborne biological particulates
- ✓ The 3 minute setup time should be factored into any procedure and should not delay any medical intervention

Contraindications

The NPS is contraindicated for use:

- During surgical procedures
- On patients needing 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
- On patients 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 the Instructions for Use (IFU)
- In elderly care centers – it is only for use in a hospital environment
- In ambulance transport

Warnings and Cautions:

- NPS use cannot exceed one 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, SpO2 levels, vital signs, electrocardiogram (EKG), and EtCO2, if available, during transport.
- Flammability of NPS has not been tested; no interventions that could be flammable source should be used within or near the NPS
- Device materials may cause allergic reaction
- Remove NPS and use standard of care if there is difficulty visualizing or identifying anatomical landmarks/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, electrocardiogram (EKG), and $EtCO_2$, if available. If $EtCO_2$ monitoring is not available, then use of the NPS should be limited to no more 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.

What are known and potential benefits and risks with NPS?

Known and potential benefits of NPS include:

- May prevent or minimize risk of HCP exposure to pathogenic biological airborne particulates
- May aid as an extra layer of barrier protection in addition to PPE
- May allow a potentially safer method to perform standard, non-invasive respiratory treatments by containing and evacuating pathogenic biological airborne particulates
- Ability to transport a suspected/confirmed COVID-19 patient inside a hospital without contaminating surroundings and other personnel

Known and potential risks of NPS include:

How can I learn more?

CDC websites:
General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Infection Prevention and Control Recommendations in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html
FAQ on Personal Protective Equipment: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

FDA websites:
General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

- Device malfunction may lead to oxygen deprivation of the patient and patient injury
- Failure of the device may also increase the risk of possible contamination of HCP, or increased risk of release of pathogenic biological airborne particulates to the local environment and possible contamination of people in the surrounding area
- Failure of the device to work properly may lead to inadequate oxygen levels in the patient's bloodstream, which could cause a condition known as hypoxia, or elevated carbon dioxide levels in the bloodstream and lead to a condition known as hypercarbia
- Device may interfere with procedures conducted on the patient
- Inappropriately assembled device may lead to failure of the device to properly isolate patient
- Accidental device folding or blockage of airflow inlets may result in patient injury
- Delayed emergency removal of the device may result in patient injury
- Patient may have an allergic reaction to device materials

What are the alternatives to the NPS during the COVID-19 pandemic?

- There are no approved available alternative devices. FDA has issued EUAs for other similar products that can be found at:
- https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

What is an Emergency Use Authorization (EUA)?

The United States Food & Drug Administration (FDA) has made the emergency use of the NPS available under an emergency access mechanism called an EUA.

The EUA is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The authorized use of the NPS under this EUA has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the device that meets certain criteria for safety, performance, and labeling, and that it may be effective in treating patients with COVID-19.

The EUA for the NPS is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used).

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Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**