

You are being given this Fact Sheet because the Negative Pressure SteriDome (hereafter “NPS”), a disposable negative pressure chamber will be used on you.

The NPS is authorized to be used by healthcare providers (HCP) as an extra 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 patients with suspected or confirmed diagnosis of COVID-19 when performing certain medical procedures, such as placing a breathing tube in your trachea (windpipe) to support your breathing and providing breathing treatments, or during patient transport within the hospital during the COVID-19 pandemic. NPS must be used with healthcare facility-provided supplemental oxygen for patients.

This Fact Sheet contains information to help you understand the benefits and risks of using NPS for preventing the spread of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

For the most up to date information on COVID-19, please visit the Center for Disease Control and Prevention (CDC) Coronavirus Disease 2019 (COVID-19) webpage:

- <https://www.cdc.gov/COVID19>

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

What is the NPS?

NPS is a negative pressure chamber comprised of a clear, disposable plastic that provides a portable frame-reinforced lightweight chamber (1lb) and is designed to cover your head and upper body. NPS incorporates

access ports through which your provider’s hands may have access to you during certain medical procedures. The negative pressure environment is generated using a hospital-provided vacuum source along with medical oxygen to help protect HCP from pathogenic biological airborne pathogens.

NPS is limited to use in a hospital setting, including for transport within a hospital setting for temporary transfer with direct admission within the hospital, only in the presence of a registered nurse or physician.

You have the option to refuse this product. If you choose to decline use of this device, you should discuss any alternative options or questions/ concerns with your health care provider.

How does the NPS work?

Hospital-provided suction equipment is connected to the NPS to create negative pressure while the patient receives medical air or oxygen. Negative pressure inside the enclosure should help keep particles from sneezes, coughs, and talking inside the enclosure to reduce HCP risk of infection.

Why will the NPS be used as part of my care?

Your HCP has selected to use the NPS for your COVID-19 treatment and care, because it allows doctors, nurses and other HCP to attend to you while reducing exposure to the virus that causes COVID-19. The NPS will allow your health care providers to treat you from outside of the isolation chamber.

What are known and potential risks and benefits of the NPS?

Known and Potential Risks

- 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

How can I learn more? The most up-to-date information on the COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

Emergency Use of Negative Pressure SteriDome (NPS) during the COVID-19 Pandemic

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

Known and Potential Benefits

- 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

Is the NPS Food and Drug Administration (FDA)-approved or cleared?

No. The NPS is not FDA-approved or cleared. The FDA has authorized this use of the NPS through an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

The United States FDA has made the NPS available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service declaration that circumstances exist to justify the

emergency use of medical devices during the COVID-19 pandemic.

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, 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 product meets certain criteria for safety, performance, and labeling and may be effective for use by HCP as an extra layer of barrier protection in addition to PPE, to prevent HCP exposure to pathogenic biological airborne particulates by providing temporary isolation of hospitalized patients with suspected or confirmed COVID-19, at the time of airway management when performing airway-related medical procedures, or during certain transport of such patients within the hospital, during the COVID-19 pandemic.

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

What are the approved alternatives?

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>

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