

FACT SHEET FOR PATIENTS

Emergency Use of the Negative-pressure Respiratory System with Advanced Ventilation Return (NRS AVR-100)

June 13, 2020

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because a Negative-pressure Respiratory System with Advanced Ventilation Return (hereafter referred to as the “NRS AVR-100”) will be used on you.

This device 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 isolation of patients with suspected or confirmed diagnosis of COVID-19 when performing medical procedures, such as placing a breathing tube in your trachea to support your breathing and providing breathing treatments, or during patient transport within a hospital setting for temporary transfer only for direct admission within the hospital during the COVID-19 pandemic.

This Fact Sheet contains information to help you understand the benefits and risks of using the NRS AVR-100 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, which can cause mild to severe respiratory illness, has now spread globally, including to 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.

How can I learn more? The most up-to-date information on 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.

What is the NRS AVR-100?

The NRS AVR-100 is a negative pressure, clear, rigid chamber that attaches to standard hospital or surgical beds and is placed around the head, neck, and shoulders of the patient. Access holes sealed by rubber shrouds built into the chamber allow for isolated patient access. The negative pressure environment is generated via a portable suction or negative pressure pump equipped with in-line high-efficiency particulate air (HEPA) filter suction devices with an in-line filter or via the healthcare facility wall-mounted suction.

The NRS AVR-100 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.

How does the NRS AVR-100 work?

Suction and oxygen are connected to the NRS AVR-100 to create negative pressure and deliver oxygen, respectively. Negative pressure inside the enclosure should help keep particles from sneezes, coughs, and talking inside the enclosure.

What are known and potential benefits and risks with the NRS AVR-100

Known and Potential Benefits

- Prevent/minimize risk of HCP exposure to virus by providing an extra layer of barrier protection in addition to PPE.
- Allow safer method for HCP to perform standard, non-invasive respiratory treatments by containing and evacuating the airborne particulates inside of the device.

Known and Potential Risks

- Device malfunction may lead to patient oxygen deprivation.
- The failure of the device may also increase the risk of release of the virus outside of the device to contaminate HCP or people in the surrounding area.
- Allergic reaction to non-biocompatible materials.

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- Inadequate cleaning and disinfection of the NRS AVR-100 between patient uses may result in increased risk of transferring contaminants which may lead to infections.
- Device malfunction may lead to excess carbon dioxide being built up in the bloodstream a condition known as hypercapnia in patients that are not being mechanically ventilated while within the NRS AVR-100.

What is an Emergency Use Authorization (EUA)?

The FDA has made the NRS AVR-100 available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of HHS's declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The NRS AVR-100, made available 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, and based on the totality of scientific evidence available, it is reasonable to believe that the NRS AVR-100 may be effective for use by HCPs as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates during transport of patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing medical procedures related to airway management and breathing treatments on such patients during the COVID-19 pandemic, and the known and potential benefits of the NRS AVR-100, for such use, outweigh the known and potential risks.

The EUA for the NRS AVR-100 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).

How can I learn more? The most up-to-date information on 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.