

SuperNO₂VA Product Information: COVID-19

April 2020

SuperNO₂VA™ nasal PAP ventilation device

SuperNO₂VA is used to pre-oxygenate, maintain ventilation, rescue ventilation, and relieve upper airway obstruction due to decreased level of consciousness

Cat. no.: **SSN-20, SSL-20, SNM-20, SNL-20**

Designed to connect to an oxygen supply source and use gas flow and/or resistance to generate positive pressure to support patients in respiratory insufficiency or failure.

SNM-20 SuperNO₂VA Nasal Interface Medium

SNL-20 SuperNO₂VA Nasal Interface Large

SSM-20 SuperNO₂VA Satellite Kit Medium

SSL-20 SuperNO₂VA Satellite Kit Medium



Key Reminders

- SuperNO₂VA™ Nasal PAP Device and System combines a no-leak nasal mask with an anesthesia/hyperinflation bag, an adjustable pressure-limiting (APL) valve and is connection-ready for wall oxygen or an oxygen tank source. This simple set up allows the device and system to be used in any environment that has an oxygen supply.
- Keeping the oxygen flow between 8 to 15 liters per minute (LPM) will reduce the risk of over-pressurization.
 - To reduce the risk of drying out nasal mucosa, limit oxygen flow less than 15 LPM as the SuperNO₂VA™ Nasal PAP Device and System uses non-humidified oxygen.
 - To reduce the risk of re-breathing CO₂, ensure the oxygen flows are greater than 8 LPM.
- The device and system do not require a humidifier.
- The clinician should occasionally monitor the patient's oxygen saturation to ensure therapy is effective.
- All healthcare professionals to review IFU 36-23405 (mask only) and/or 36-23406 (system) as well as be trained using the public training video:
<https://www.youtube.com/watch?v=iGCf3xLnhPk&feature=youtu.be>
- This device and system are indicated for operative care – should it be used externally from op care; it shall be used only under the supervision of a trained healthcare professional.
- In the event of a delayed allergic reaction, discontinue use of the SuperNO₂VA™ Nasal PAP Device and System immediately.

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RISKS

- SuperNO₂VA Device and System **does not** connect to alarms and therefore, will not alert the clinician if pressure is too high or too low.
- The nasal mask is completely sealed and applies pressure to the skin, there is a risk of a pressure ulcer. During use, a trained provider should occasionally loosen the nasal mask to permit blood circulation within skin capillaries to reduce the risk of a pressure ulcer. Please routinely inspect skin and reposition frequently to reduce the risk of skin ulcer.
- SuperNO₂VA is designed to support and sustain life. If this system is not used properly in accordance with instructions and occasionally monitored by trained health care professionals, a risk of serious injury or death can occur.
- Risks are related to any use of SuperNO₂VA products other than that for which they are indicated. Clinicians considering such use during the COVID-19 pandemic must weigh the risks and benefits and ensure proper training and safe handling of the products.

Filter **

Vyaire filters are intended to be used to provide filtration to reduce possible cross contamination between patients and equipment.

Cat. no.: 003007

The following filter should be used to provide filtration and passive humidification

003007 HMEF HEPA large volume with gas sampling port, Connection: 15 mm male for Y-piece; 15/22 mm ISO female/male for ET tube, closed suctioning system, etc. Standard luer lock gas sampling port (dry, filtered side)



** Note: this product is recommended by Vyaire Medical as a potential filter. However, any HEPA or bacterial virus filter with a compatible 15mm ISO port is acceptable to reduce aerosolization.

Key Reminders

- Connect a filter to the circuit port on the SuperNO₂VA nasal mask to reduce the risk of aerosolization.

RISKS

- Consider flow resistance (3.3 cmH₂O for 003007) and dead space (95mL for 003007) for any filter you attach.