

CLINICAL SUMMARY

SuperNO₂VA™ Nasal Positive Pressure System

Delivers positive airway pressure to stent open the upper airway, allowing for the preoperative delivery of positive pressure ventilation and oxygen for patients with a decreased level of consciousness. The SuperNO₂VA™ nasal positive pressure ventilation device is available in medium and large sizes and is offered as a standalone mask with a head strap and as a system, packaged with a hyperinflation bag. These configurations offer flexibility as they allow the SuperNO₂VA™ nasal positive pressure ventilation device to be used with either an anesthesia machine or with only an oxygen flow meter.

STUDY	TYPE OF STUDY	SPECIALTY	PATIENT POPULATION	SET-UP / INTERVENTION	CONCLUSION
<p>Comparison of a simplified nasal continuous positive airways pressure device with nasal cannula in obese patients undergoing colonoscopy during deep sedation: A randomized clinical trial</p> <p>Tap below to read study</p> <p>Bai; 2019</p>	Randomized controlled trial	Elective colonoscopy	136 patients, BMI 30 to 50 kg m2	Nasal cannula vs. SuperNO ₂ VA™	<p>Randomized controlled trial showing the improved performance of SuperNO₂VA™ vs nasal cannula (control group).</p> <p>Application of a nasal mask at a target CPAP of 10cmH2O improves ventilation and decreases the frequency and severity of hypoxaemia.</p>
<p>Treating oxygen failure in angioedema: a case series employing noninvasive nasal positive pressure with the SuperNO₂VA device</p> <p>Tap below to read study</p> <p>Bastien; 2019</p>	Case series	Cases of angioedema with inadequate oxygenation	4 patients (age 54 to 67 years)	Treating oxygen failure	<p>The SuperNO₂VA™ made it easy to achieve a proper mask seal and nasal positive pressure transmitted unimpeded to the hypopharynx and had the added benefit of displacing the soft palate and tongue anteriorly, off the pharyngeal airway. Ventilation via a nasal mask may be superior to full facemask in this setting. Where possible, nasal oxygenation should be continued during endotracheal intubation.</p>
<p>SuperNO₂VA™ and general anesthesia postoperative care</p> <p>Tap below to read study</p> <p>Burnett; 2020</p>	Randomized controlled trial	Scheduled elective surgery	80 hypoxic adult patients, ASA I-IV, with a body mass index (BMI) > 35 kg/m2	Standard of care (n=40) vs. SuperNO ₂ VA™ (n=40)	<p>SuperNO₂VA™ is a viable alternative oxygen delivery device, as compared to a simple mask or nasal cannula, in the postoperative setting. The SuperNO₂VA™ may be an improved method for oxygenation and ventilation in patients suffering from a history of obstructive sleep apnea or other upper airway obstruction.</p>
<p>Using the SuperNO₂VA Device on a Patient With a Known Difficult Airway: A Case Report Facilitating Fiberoptic Intubation and Postoperative Nasal Positive Pressure</p> <p>Tap below to read study</p> <p>Cataldo; 2019</p>	Case Report	Operating room, transport and recovery	patient (46 yr. / man) sleep apnea and anticipated difficult airway	Use of SuperNO ₂ VA™ during transport and non-operating room	<p>Case report suggests that SuperNO₂VA™ provides non- invasive nasal positive pressure in the operating room. Its application during transport and in non- operating room settings and may prove to be an advantage when treating high-risk patients with upper airways obstruction.</p>
<p>The SuperNO₂VA™ to treat upper airway obstruction and respiratory compromise after major head and neck surgery: a case report</p> <p>Tap below to read study</p> <p>Cataldo; 2019</p>	Case Report	Major head and neck surgery, emergency setting	Patient who underwent emergent cervical decompression and fusion with carpectomy following blunt force trauma	Nasal positive pressure used to maintain upper airway patency and provide ventilatory support during emergence	<p>SuperNO₂VA™ with a hyperinflation bag and oxygen source provide nasal PAP for maintaining upper airway patency and providing ventilatory support postoperatively and during transport after major head and neck surgery. Further they show the advantages of SuperNO₂VA™ compared to nasal cannula, high flow nasal cannula, and nasal CPAP.</p>



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<p>Perioperative Care of the Obese Cardiac Surgical Patient</p> <p>Tap below to read study</p> <p>Chacon; 2018</p>	Review Article	Cardiac surgery	Literature Review	Review of the physiologic abnormalities and clinical implications of obesity in cardiac surgery and the recommendations for anesthesiologists to optimize perioperative care of the obese cardiac surgical patient	Obese and morbidly obese patients increasingly are presenting for cardiac surgery and pose challenges for the cardiac anesthesiologist. Morbid obesity is associated with higher morbidity and mortality after cardiac surgery.
<p>Nasal positive pressure with the SuperNO₂VA™ device decreases sedation-related hypoxemia during pre-bariatric surgery EGD</p> <p>Tap below to read study</p> <p>Dimou; 2018</p>	A prospective observational study was	Esophagogastroduodenoscopy in patients undergoing bariatric surgery	56 morbid obese patients with obstructive sleep apnea	Use of the SuperNO ₂ VA™ as alternative as the standard of care	The study demonstrated that patients with higher BMI, higher ASA classification, and OSA were more likely to have the SuperNO ₂ VA™ device used; yet, paradoxically, these patients were less likely to have issues with desaturation events. Use of SuperNO ₂ VA™ can optimize care in this challenging patient population by minimizing the risks of hypoventilation.
<p>Evaluation of SuperNO₂VA™ mask technology in a clinical setting: A pilot study</p> <p>Tap below to read study</p> <p>Ghebremichael; 2017</p>	Observational study	Pre-induction, post-induction and laryngoscopy	30 adult patients	Anesthesia and tracheal intubation for nasal oxygenation and ventilation during pre-induction, post-induction, laryngoscopy	The SuperNO ₂ VA™ nasal mask provided adequate oxygenation and successful ventilation in 29 of 30 patients, resulting in an overall success rate of 97%. This study demonstrated that the SuperNO ₂ VA™ mask facilitates non-invasive positive pressure ventilation while providing adequate oxygenation and ventilation during pre-induction, post-induction, laryngoscopy, and tracheal intubation in elective surgical patients.
<p>Oxygenation Performance of Different Non-Invasive Devices for Treatment of Decompression Illness and Carbon Monoxide Poisoning</p> <p>Tap below to read study</p> <p>Köhler; 2022</p>	Randomized clinical trial	Healthy volunteers	30 healthy volunteers	Comparison of eight noninvasive oxygen systems that may be used in DCI or COI on pO ₂ , pCO ₂ , and pH and their subjective comfort: nasal cannula, non-rebreather mask, AirLife Open mask, Flow-Safe II CPAP device, SuperNO ₂ VA nasal PAP device, all operated with 15 L/min constant flow oxygen; nasal high-flow (50 L/min flow), non-invasive positive pressure ventilation, and a standard diving regulator (operated with pure oxygen)	A standard diving regulator and the SuperNO ₂ VA device were equally effective in providing highest physiologically possible pO ₂ as compared to nasal high-flow and NPPV.
<p>SuperNO₂VA™ Nasal Mask Ventilation Maintains Oxygenation during Deep Sedation in High-Risk Patients: A Case Series</p> <p>Tap below to read study</p> <p>Kozinn; 2018</p>	Case series	Endoscopic gastroduodenoscopy	10 patients with BMI ≥ 34.4;	High risk patients or diagnosed with, obstructive sleep apnea undergoing deep sedation	With the SuperNO ₂ VA™ securely placed, 0/10 patients experienced upper airway obstruction and the lowest oxygen saturation was 98.0%. The observations of this case series suggest that a pressurized nasal ventilation mask may be a preferable alternative to improve oxygenation and ventilation in high-risk patients during deep sedation.
<p>A nasal ventilation mask for a morbidly obese patient with OSA and atrial fibrillation undergoing cardioversion</p> <p>Tap below to read study</p> <p>Kozinn; 2018</p>	Case report	Cardioversion for atrial fibrillation	50 yo male with morbid obesity (BMI 47.2), OSA, HF, AF	Preoxygenation with nasal cannula; SuperNO ₂ VA™ if required	Patient desaturated during TEE; SuperNO ₂ VA was applied and procedure was completed. Attempts at cardioversion were unsuccessful. During the follow-up procedure, SuperNO ₂ VA was used at the outset. Cardioversion was successful.



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<p>Non-invasive respiratory support in the management of COVID-19: Report of a series using a nasal CPAP mask</p> <p>Tap below to read study Betancur; 2021</p>	Case series	Respiratory failure due to COVID-19	14 inpatients receiving NIV CPAP presenting	To describe the use of SuperNO ₂ VA™ in patients with respiratory failure due to COVID-19	Anesthesiologists and respiratory specialists implemented the use of NIV CPAP with SuperNO ₂ VA™ to help meet the high care demand of patients in respiratory distress. Although the SuperNO ₂ VA was not originally developed for the management of patients in respiratory failure or distress related to COVID-19, this case series demonstrates it can be used with mostly favorable results.
<p>Shoulder Surgery using Combined Regional and General Anesthesia versus Regional Anesthesia and Deep Sedation with a Non-Invasive Positive Pressure System: A Retrospective Cohort Study</p> <p>Tap below to read study Soberon; 2021</p>	Retrospective case control study	Shoulder surgery	60 patients	Using deep sedation and interscalene block versus general anesthesia and cervical paravertebral or interscalene block	This study showed that SuperNO ₂ VA™ facilitated the performance of deep sedation for shoulder surgery with an interscalene block for both shoulder arthroscopic procedures and shoulder arthroplasty. This technique was associated with avoidance of mechanical ventilation, decreased anesthesia time, use of vasopressors, and need for urinary catheter placement.
<p>Nasal Ventilation Mask for Prevention of Upper Airway Obstruction in Patients With Obesity or Obstructive Sleep Apnea</p> <p>Tap below to read study Willard; 2019</p>	Comparative observational design	Outpatient endoscopy clinic	100 patients with obstructive sleep apnea	50 patients with SuperNO ₂ VA™ vs 50 with standard of care	This study evaluated the performance in an outpatient endoscopy clinic. The study concluded that SuperNO ₂ VA™ not only offers ventilation in sedated patients but also has the ability to provide positive pressure assistive breaths.