SuperNO$_2$VA™ Et

Demonstrated value in patient care and cost avoidance

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Executive Summary

Clinical Challenge:	Clinical Solution:
1) Reduction in Respiratory Complications and Airway Interventions	**Nasal Positive Airway SuperNO$_2$VA™ Et**
2) Airway Management Option for Obese and OSA patients	Proven reduction in hypoxemia and airway interventions with high risk patients under deep sedation

- Five to 42% of sedated patients may have upper airway obstruction leading to hypoxia and hypoventilation[1 (Friedrich-Rust M)]
- Obesity and OSA risk factors increase incidence of airway obstruction 2-9 times over normal weight patients [2 (Yilmaz M)]
- In GI procedures in a non-OR anesthesia settings, 50% have some form of respiratory complication such as desaturation (SpO_2<90%)[3, 4 (Perry , Sidhu)]
- Strategies for implementing nasal ventilation mask, as standard therapy for deep sedation are becoming increasingly important.[5 (Fukuda K)]
- Use of SuperNO$_2$VA™ airway device offers a clinical advantage compared to the current standard of care.[6 (Dimou)]

Procedures and Specialists that might be applicable

• EGD • Endoscopy • Laryngoscopy • Otolaryngology • Bariatric Surgery • Orthopedic Surgery

Background: Deep sedation clinical challenges

Sedation procedures are on the rise: Sedation and anesthesia are an important means of providing patient comfort, safety, and clinical stability during invasive and uncomfortable medical procedures. The use of procedural sedation is considered to be on the rise.[10 (Saunders)] Upper airway obstruction induced by sedation may lead to hypoxia and hypoventilation, occurring in 5% to 42% of all sedated patients.[1 (Friedrich-Rust M)] There is a tremendous need for an airway device that supports airway patency during sedation, thereby reducing the risk of airway obstruction and other adverse events.[11 (Kozin)]

Incidence of complex patients are on the rise: There are increasing challenges for airway management with the convergence of increasing patient obesity; the expansion of minimally invasive procedures[11 (Kozin)] ; and the prevalence of obstructive sleep apnea (OSA).[13, 14 (M. Roesslein and J. Cooksey)]

OSA: In the general population, OSA is estimated between 3 and 24%, however, its prevalence in patients undergoing surgery is 24-41% but can be as high as 70% in high-risk patients such as those that are morbidly obese.[13, 14 (M. Roesslein and J. Cooksey)] OSA is also an independent risk factor for perioperative cardiopulmonary adverse events[15 (Patel)]

High BMI and OSA: Obese patients are at increased risk for hypoxemia, hypoventilation and upper airway obstruction during deep sedation due to a reduced functional residual capacity, increased oxygen consumption, and excess fat deposition within the lateral pharyngeal walls that results in a smaller than normal pharyngeal volume. These are further complicated by the drug-induced relaxation of upper airway muscle activity and suppression of protective arousal responses.[16, 6, 17 (Hillman, Dimou, Wani S)]

During sedation obese patients with obstructive sleep apnea are predisposed to episodes of desaturation in the perioperative period due to alterations in their respiratory physiology such as decreased lung and chest wall compliance, increased airway resistance, decreased respiratory muscle strength, increased work of breathing, and alterations in ventilation/perfusion ratio. These physiologic alterations are further exacerbated by the administration of anesthetics, sedatives and opioids.[18 (J. Guimaraes)] Obstructive sleep apnea is an independent risk factors with odds ratios 2-9 times that of normal weight patient.[2 (Yilmaz M)]

In GI procedures in a non-OR (NORA) anesthesia setting 50% have some form of respiratory complication such as desaturation (SpO_2<90%)[3,4 (Perry and Sidhu)]

Nasal positive pressure (NPP) increases end expiratory lung volume and decrease small airway closer by opening collapsed alveoli the fore improving end-expiratory lung volume.[7 (Soberon)] In OSA patients, nasal positive pressure provides ventilatory support while maintaining upper airway patency.[7 (Soberon)]

Treatment Options: The current standard of care (SOC) for sedation procedures are passive oxygenation devices (NC and face mask) with continuous capnography monitoring; however, the incidence of hypoxemia and other respiratory adverse events remains high with passive oxygenation devices.[6 (Dimou)] There is a need for procedural airway management for higher risk patients undergoing deep sedation with co-morbidities such as high BMI, obstructive sleep apnea or larger neck circumference.[12, 13 (Kozzin)] Strategies for implementing nasal ventilation mask, as standard therapy for deep sedation is becoming increasingly important.[5 (Fukuda K)] Use of SuperNO$_2$VA™ device can offer a clinical advantage compared to the current standard of care for addressing hypoxemia and other adverse events during sedation.[6 (Dimou)]

SuperNO$_2$VA™ Et

The SuperNO$_2$VA™ Et Mask is a nasal mask that creates a seal when positioned over a patient's nose to direct anesthesia gas, air, and / or oxygen to the upper airway during the continuum of anesthesia care.

It has a means for sampling expired gases from the patient's exhaled breath from the oral / nasal areas. FDA K173147

Nasal Positive Pressure: Non-invasive positive pressure ventilation increases end expiratory lung volume and decreases small airway closure by opening collapsed alveoli, thereby improving end-expiratory lung volume and respiratory mechanics.[19 (J.M.S.M. Delay)]

The SuperNO$_2$VA™ Et sealed nasal ventilation mask meets ASA and AARN criteria of providing supplemental oxygen, and when connected to either an anesthesia circuit or hyperinflation bag generates positive pressure while allowing for $ETCO_2$ sampling. The device maintains upper airway patency and ventilatory support, while delivering a high FiO_2 at titratable positive pressures. Its ability to generate positive pressures to overcome Upper Airway Obstruction (UAO) and airway collapse can reduce the need for endotracheal intubation and its associated complications. Furthermore, the ability to monitor $ETCO_2$ provides timely detection of apnea, even at high-flow rates, due to it being a nearly closed system.[11, 12 (Kozin)]

The nasal mask functions through the following principles.

- The mask together with the hyperinflation bag generates nasal positive pressure; thus, it is effective in treating anesthesia-induced upper airway obstruction which commonly occurs in the obese population undergoing deep sedation.
- Improved breathing efficiency from dead space flushing.
- The mask connected to the hyperinflation bag is used with an oxygen fresh gas flow of up to 15 L per min and a reservoir bag of 2 L, reducing entrainment of room air during inspiration, resulting in a functional increase in FIO_2.[6 (Bai)]

The ASA Committee of Standards and Practice Parameters recommends providing every patient with a continuous course of passive supplemental oxygen and continuously monitoring oxygenation and ventilation during moderate or deep sedation procedures[19 (Weaver J. and Dimou)]

Capnography: End-tidal monitoring provides qualitative information during sedation that is essential regarding patient apnea.[12 (Kozzin)] Based on performance testing the use of the SuperNO$_2$VA™ Et offers significantly more accurate measurement of $EtCO_2$ than other $EtCO_2$ sampling line. Measurements of $EtCO_2$ within the SuperNO$_2$VA™ Et are accurate over a range of CO_2 concentrations, respiratory rates, tidal volumes, and O_2 flows, and were not different for oral and nasal breathing.[21 (Pedro)]

Oxygen Flow: Flow dependent positive pressure requires only 10-15 l / mm of oxygen to provide expiratory pressure to maintaining airway patents.[22 (S. Ghebremichael)]

Passive oxygenating devices have the ability to provide higher concentrations of oxygen, however, they are incapable of generating positive pressure, which is required in order to maintain airway patency and provide ventilatory support in the event of UAO and respiratory depression. High flow nasal oxygen with flow rates of 4- to 60 L/min dilutes exhaled CO_2, thereby precluding the ability to monitor ed-tidal CO_2.[11 (Kozzin)] High Flow Nasal cannula is challenged to monitor $ETCO_2$ due the high flow of O_2 causing dilution.[23 (Klare)]

Clinical Evidence

Comparative Studies Addressing Sedation Adverse Events

Orthopedic Surgery	Colonoscopy	Endoscopy
Shoulder Surgery Study[7 (Soberon)] Regional Blocks combined with Deep sedation + non-invasive positive pressure system (SuperNO$_2$VA™) vs general anesthesia **DS + NPP Results:** • Lower Induction and emergence-related anesthesia times ($p < 0.0001$) • Less total sedation time (20 minutes less) • Higher oxygen saturation (SpO_2) on PACU arrival and one hour post. • Greater ease in patient positioning. • No patient conversion to general anesthesia • No additional airway support measures	**Study**[8 (Bai)] Deep sedation + Nasal positive pressures (NPP) vs NC in obese patients. **NPP Results:** • NPP improves ventilation and decreases frequency and severity of hypoxemia, reduces airway interventions and improved minute ventilation • Lower hypoxemia events 22% (NC) vs 5% (NPP) $p=0.004$ • Less interventions (chin lift/jaw thrust) with NPP (NC 22% vs NPP 63%). • Significant improvement in time from Anesthesia Induction to first Airway Intervention ($p<0.001$) with NPP	**Study**[6 (Dimou)] Pre-bariatric surgery EGD NPP (SuperNO$_2$VA™ vs NC) **Results:** • Reduced number of clinically significant hypoxemic events • SuperNO$_2$VA™ Et device allowed for better oxygenation **Study**[9 (Willard)] Deep sedation for colonoscopy and EGD high BMI & OSA patients **Results:** • Lower incidence of Hypoxemia • Non-Nasal Ventilation Mask (NVM) patients had a 3 x greater chance of having at least 1 occurrence of oxygen saturation <90% than the NVM group

The following studies highlight SuperNO$_2$VA™ Nasal Positive Pressure Mask system measured positive outcomes and demonstrate a decrease in adverse events occurrence such as hypoxemia and interventions that may lead to delayed procedure time and possible inpatient admittance.

- **Orthopedics:** Comparative retrospective case-controlled study with shoulder surgery with regional blocks combined with either general anesthesia or deep sedation with non-invasive positive pressure system (SuperNO$_2$VA™). This study demonstrated that non-invasive positive pressure ventilation facilitated the performance of deep sedation for shoulder surgery with an interscalene block for both shoulder arthroscopic procedures and shoulder arthroplasty. Deep sedation with SuperNO$_2$VA™ was associated with fewer episodes of intraoperative hypotension; avoidance of mechanical ventilation; decreased anesthesia time and lower intraoperative non-surgical time; with no use of vasopressors or urinary catheters; and a greater ease in patient positioning. Total anesthesia time for deep sedation using the SuperNO$_2$VA was 22 minutes less than the GA group and no patient who received deep sedation required conversion to general anesthesia or required additional airway support measures.[7 (Soberon)] Some additional study outcome highlights:

Study Events	Deep Sedation with SuperNO$_2$VA™	General Anesthesia	P Values
OR to anesthesia ready	12 min	31 min	P<0.001
Induction to emergence time	17 min	39 min	P<0.001
IV Fluids	451ml	1312ml	P<0.001
Oxygen saturation (<95% SpO$_2$)	5%	40%	
Oxygen saturation at 1 hr. (post-surgery)	0	28%	
Total Anesthesia Time	22 minutes less than GA		

- **EGD and Bariatrics:** An RCT study with nasal positive pressure using the SuperNO$_2$VA™ device decreases sedation-related hypoxemia during pre-bariatric surgery EGD. High fraction inhaled oxygen and titratable positive pressure compared to NC sealed nasal positive airway pressure mask study measuring sedation related adverse events.
  - Hypoxemia and desaturation events were significantly lower in the SuperNO$_2$VA™ group (11.5% vs. 46.7%, p = 0.004)
  - Median lowest oxygen saturation was higher in the SuperNO$_2$VA™ group (100% vs. 90.5%, p < 0.0001)
  - Procedural Interruptions to allow for bag ventilation were zero in SuperNO$_2$VA™ group and three in the NC group (p=0.24).

  The SuperNO$_2$VA™ device allowed for better oxygenation of bariatric patients undergoing EGD and reduced the number of clinically significant hypoxemic events.[6 (Dimou)]

- **Colonoscopy:** Comparison study of a simplified nasal continuous positive airways pressure (NPPM) device with nasal cannula (NC) in obese patients undergoing colonoscopy during deep sedation. Primary endpoint was elapsed time from anesthesia induction to first airway intervention, because it is a reliable show of the efficacy of ventilation and oxygenation without airway intervention. Results demonstrated NPPM has the following outcomes:
  - Decreased time from Anesthesia Induction to first Airway Intervention) (p<0.001)
  - Decreased the frequency and severity of hypoxemia: Hypoxemia occurred more frequently in the NC Group (22%) than in the NPPM mask group (5%) (p=0.004).
  - Reduced airway intervention (chin lift/jaw thrust): NPPM 22% vs NC 63%[8 (Bai)]

- Evaluation of SuperNO$_2$VA™ mask technology in a clinical setting. 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 with overall success rate of 97% (95% confidence interval: 83%–100%).[22 (SemharGhebremichael)]

- SuperNO$_2$VA™ Nasal Mask Ventilation Maintains Oxygenation during Deep Sedation in High Risk Patients. The NMV SuperNO$_2$VA was well tolerated and produced nasal oxygenation and positive airway pressure (PAP) that maintained oxygen saturation (SpO$_2$) > 97.0% throughout the cases in this case series report.[11 (Kozin)]

- Nasal Ventilation Mask for Prevention of Upper Airway Obstruction in Patients with Obesity or Obstructive Sleep Apnea during EGD or colonoscopy. Comparative observational study NVM (SuperNO$_2$VA) vs NC. The Non-NVM group had 3 x greater chance of having at least 1 occurrence of oxygen saturation <90% than the NVM (SuperNO$_2$VA) group.[24 (Willard)]

- A randomized controlled trial conducted to determine whether CPAP via a Nasal Ventilation Mask (NVM) ($SuperNO_2VA^{™}$) was more effective at maintaining airway patency than an oronasal mask in patients with OSA during induction of general anesthesia. Results: rate of effective tidal volume was significantly higher ($P < .01$) for NVM and the median expired tidal volume was significantly larger with NVMs ($P < .01$)[25 (Oto)]

NPP $SuperNO_2VA^{™}$ Et Through the Continuum of Care		
Pre-Op / Procedure	**During Procedure (variety of settings)**	**Post Procedure Care**
Identify to Patient	Maintains oxygen levels	Transport from procedure
Pre-oxygenation	Decreases hypoxemia events	Care during PACU
Provide with	Decreases interventions	Recover with maintaining oxygenation
Procedure Blocks		Rescue breathing capabilities

Cost avoidance and related economics

All sedation-related adverse events (AEs) increase health care costs and result in substantial delays or cancellations of subsequent procedures.[10 (Saunders)] The prevention of even minor AEs during procedural sedation may be crucial to ensuring its value as a health care service.[10 (Saunders)]

Time is a universal currency in hospital operating rooms and procedure suites.

Prevalence of each Adverse Event as a percentage[10 (Saunders)]					
Adverse Event	**Procedure Delay**	**Procedure Terminated**	**Unplanned Inpatient Stay**	**Increased LOS**	**Number of Interventions**
O_2 Desaturation Mild & Short	4.0%	5.3%	4.5%	2.2	20.8
O_2 Desaturation Mild & Long	6.3%	2.8%	3.6%	1.1	31.3
Airway Obstruction	5.0%	5.0%	5.0%	1.9	23.3
O_2 Desaturation Severe	19.1%	15.0%	20.3%	2.2	9.9

Procedural sedation carries inherent patient risks and requires careful monitoring of patients' vital signs. Both US (American Society of Anesthesiologists) and European (European Board of Anesthesiology and European Society of Anesthesiology) recommendations require minimum measures of oxygenation (pulse oximetry), circulation (non-invasive blood pressure), and ventilation (capnography).[26, 27, 10 (ASA ESA in Saunders)]

All sedation-related AEs can increase health care costs and result in substantial delays or cancellations of subsequent procedures. The prevention of even minor AEs during procedural sedation may be crucial to ensuring its value as a health care service.[(Saunders)] Despite best monitoring practices, however, adverse events (AEs) related to sedation still occur, with hypotension and hypoxemia among the most commonly reported.[10 (Saunders)]

Survey results from health care providers and payers in five countries in blinded analysis provided insight into adverse events during deep sedation procedures. Survey results from 101 providers and 26 payers respondents with the majority having >5 years of experience and performed a total of 3,430 procedural sedations per month were analyzed. The AE details occurred in clinical practice in the last year and were reported to cause procedural delays and cancellations in some patients. AEs were associated with early termination, delays in subsequent procedures: airway reposition, Increase sedation, Use of bag mask, Laryngeal mask, OA, Positive pressure, supplemental O_2 and Intubations. All AE's had cost implications.[10 (Saunders)]

Top AEs were hypotension, followed by Bradycardia, Tachycardia, Oxygen desaturation (mild, short), Hypertension, Apnea (not prolonged), Oxygen desaturation (mild, long), AW obstruction, Failed sedation, Apnea (long), Allergy, Oxygen desaturation (severe), Cardiovascular collapse, Cardiac arrest, and Seizure.

Increased costs resulting from sedation-related AEs are driven by not only the costs of interventions used to treat them but also the outcome or longer-term impact of the complication. [10 (Saunders)]
All sedation-related AEs can increase health care costs and resulted in substantial delays or cancellations of subsequent procedures. The prevention of even minor AEs during procedural sedation is crucial to ensuring its value as a health care service.[10 (Saunders)]

Additional patient and care setting considerations

Nasal Positive Pressure therapy such as the SuperNO$_2$VA™ Et can be utilized in a variety of care settings and procedures.

In the PACU as patients receiving moderate procedural sedation may continue to be at risk for developing complications after their procedure is completed due decreased stimulation from the proceduralist, delayed drug absorption after non-intravenous administration, and slow drug elimination may contribute to residual sedation and cardiorespiratory depression during the recovery period.[28 (Fuller)]

Elderly patients or patients with coexisting conditions such as obesity, chronic obstructive pulmonary disease and obstructive sleep apnea may pre-dispose them to perioperative pulmonary complications.[7 (Soberon)]

Nasal Positive Pressure along with Interscalene blocks, combined with sedation, have been used as an alternative to general anesthesia in patients undergoing arthroscopic shoulder and provides excellent intraoperative muscle relaxation, improved analgesia, fewer un planned hospital admissions, faster post-anesthesia care unit discharge times, and decreased postoperative nausea and vomiting compared to general anesthesia.[29 (A.R. Brod wn anL.J. Lehmann, G. Loosen)]

For some procedures such as orthopedic shoulder surgery, access to the patient and their airway are limited since the operating room table is generally turned away from the anesthesia workstation, and the procedures are often performed in the beach chair or lateral decubitus positions with surgical drapes limiting airway access.[7 (Soberon)]

Appendix #1

FDA STATEMENT:

FDA Approved. K173147 The SuperNO$_2$VA Et™ Device is a nasal mask with a sampling port for the nasal portion and a sampling “hood” for over the mouth. Instead of covering the full face the SuperNO$_2$VA Et™ Device design is to allow the clinician to have access to the oral cavity during a procedure but still be able to provide air, oxygen or anesthesia gases to the patient while also sampling expired gases from the nasal or oral areas.

The design incorporates the standard 15 mm male circuit connector, luer fitting for the gas sampling line and a slip-fit port for pressure monitoring or oxygen if the mask is used with a manual resuscitator or hyperinflation bag.

Indications for Use: The SuperNO$_2$VA Et™ Device is a nasal mask that creates a seal when positioned over a patient’s nose to direct anesthesia gas, air, and / or oxygen to the upper airway during the continuum of anesthesia care. It has a means for sampling expired gases from the patient’s exhaled breath from the oral / nasal areas. The SuperNO$_2$VA Et™ Device is intended for short-term < 24 hrs. for adults (<30 kg.). It is a single patient use, disposable. The SuperNO$_2$VA Et™ Device is contraindicated for use in long-term ventilation conditions and treatment of sleep apnea.

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