Making Mechanical Ventilation Safer

THE ASPIRE SUBGLOTTIC SUCTION ENDOTRACHEAL TUBE INFORMATION PACKET
How to Use this Information

The information in this packet is intended to introduce the Aspire Subglottic Suction Endotracheal tube and to provide a clear explanation of the benefits of this solution compared to single-port devices. It is meant to be a tool to help you understand how the Aspire can improve clinical care and enhance infection prevention for all patients undergoing mechanical ventilation. The information presented was assembled in conjunction with subject matter experts, and cost benefits of implementing this technology will depend on each individual healthcare system. This packet is intended to be complementary to literature reviews and other evidence-based tools and resources employed by each individual healthcare system.
To the Review Council Members,

Thank you for taking the time to review this informational packet on the NeVap Aspire Subglottic Suction Endotracheal tube (ASSET), the only FDA cleared multiport suction breathing tube. As the physician inventor of the ASSET, I developed this device after observing the short-comings of the current single suction port breathing tubes in my own patients\(^1\). Making a better breathing tube is not an economically attractive goal, but it is an impactful innovation because there is a good chance each one of us, our families, friends, and colleagues will one day benefit from this innovation.

Though robust clinical data is still being collected, clear, concise, and common sense can be helpful.

1. Subglottic suctioning is a proven cost-effective method of infection prevention\(^2\).

2. More effective, versatile, and less traumatic subglottic suctioning is better.

3. And if we only use multiport nasal gastric (NG) tubes to evacuate fluids from the stomach, why would we settle for single-port breathing tubes that rapidly become occluded by tissue\(^1\).

Sincerely,

Benjamin Wang MD  
Chief Medical Officer  
NEVAP INC

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2 Shorr AF et.al.CHEST Journal 2001;119(1):228-235
**Introduction**

The NEVAP Aspire Subglottic Suction Endotracheal Tube (Aspire) has been used in patients since the summer of 2018. Due to decisions to explore opportunities with larger medical device companies, the official commercial launch of the device was delayed until the winter of 2019. Since 2019, over 30,000 ASSET tubes have been used, without incident, in patients all over the world. Subglottic tubes impart their clinical benefit by draining secretions from the human airway, the Aspire simply removes that fluid in a more effective and less traumatic fashion.

**Background**

Mechanically ventilated patients are at high risk for ventilator-associated complications such as fluid overload, atelectasis, ARDS, and pneumonia. The endotracheal tube (ETT) plays a central role in these complications, by impairing mucociliary clearance, disrupting the cough reflex, accumulating tracheobronchial secretions and providing a pathway for bacterial laden secretions to leak into the lower airways.²,³
Secretions from the stomach, oral cavity, and sinus continuously accumulate in the airway of the unconscious patient and pool above the cuff of the endotracheal tube. These pooled, bacterial laden secretions are the cause of tracheobronchial colonization and Ventilator-Associated Pneumonia (VAP). Sealing the airway and draining fluid are widely accepted interventions.

![Diagram of Bacterial-Laden Secretions and Subglottic Port]

Millions of US patients undergo invasive mechanical ventilation annually, putting them at risk for mortality related to pneumonia and infections. Pneumonia affects approximately 10% of chronically ventilated patients and increases attributed mortality by 9-13%, adds $43,000 in additional treatment costs and increases average hospital stays by 8-14 days.

### Table 3. Costs in a Matched Cohort of 2,144 Patients with Ventilator-Associated Pneumonia (VAP) and 2,144 Patients without VAP

<table>
<thead>
<tr>
<th>Outcome type</th>
<th>Cost, dollars, mean ± SD</th>
<th>P</th>
<th>Difference in dollars (%)</th>
</tr>
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<tbody>
<tr>
<td>Hospitalization</td>
<td>99,598 ± 86,359</td>
<td>&lt;.0001</td>
<td>39,828 (40.0)</td>
</tr>
<tr>
<td>Nursing time</td>
<td>3,369 ± 16,487</td>
<td>.568</td>
<td>389 (11.5)</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>14,345 ± 16,992</td>
<td>&lt;.0001</td>
<td>5,798 (40.4)</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>1,947 ± 4,095</td>
<td>&lt;.0001</td>
<td>936 (48.1)</td>
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<tr>
<td>Vancomycin</td>
<td>327 ± 564</td>
<td>&lt;.0001</td>
<td>79 (24.2)</td>
</tr>
<tr>
<td>Propofol for sedation</td>
<td>947 ± 1,768</td>
<td>&lt;.0001</td>
<td>362 (38.2)</td>
</tr>
<tr>
<td>Ventilator</td>
<td>4,710 ± 6,251</td>
<td>&lt;.0001</td>
<td>2,526 (53.6)</td>
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<tr>
<td>Ventilator in ICU</td>
<td>3,716 ± 4,479</td>
<td>&lt;.0001</td>
<td>1,807 (48.6)</td>
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<tr>
<td>Respiratory therapy</td>
<td>2,650 ± 4,007</td>
<td>&lt;.0001</td>
<td>1,154 (43.5)</td>
</tr>
<tr>
<td>Chest x-rays</td>
<td>1,762 ± 1,594</td>
<td>&lt;.0001</td>
<td>753 (42.7)</td>
</tr>
</tbody>
</table>

**NOTE.** ICU, intensive care unit; SD, standard deviation.

* Costs represent medical direct and indirect costs (not Medicare charges). Costs were not additive (e.g., antibiotic and propofol costs were a subset of pharmacy costs).
Cuff Sealing Myths

Other medical device companies have marketed the idea that low pressure/high volume polyurethane cuff balloons seal the airway to fluids and prevent aspiration. However, there is insufficient proof to support this claim and many YouTube advertisements show leakage of fluid is rapid in all cuffs after only a few minutes, even under ideal conditions.

https://www.youtube.com/watch?v=BMZG0Xl03iA&t=1s

When polyurethane cuffed tubes were studied in live pigs and mechanically ventilated for between 3 and 6 hours, 100% were found to have aspiration that was confirmed to start in the oral cavity\(^8\). A similar experiment demonstrated that 9 in 10 abdominal surgery patients experience aspiration of secretions into the trachea and that post-operative respiratory complications could be the consequence.\(^{11}\)
Subglottic Suction Drainage
Based on clinical evidence, subglottic endotracheal tubes are recommended by the CDC, ATS/IDSA, AACN, SHEA, and AHRQ. Seven meta-analysis based on hundreds of randomized and retrospective studies have all concluded that subglottic suction drainage significantly reduces pneumonia incidence by 44-60%, reduces duration of mechanical ventilation and delays onset of VAP.12,13,14,15,16,17,18

Single-port Endotracheal Tubes
However, most US hospitals do not use subglottic suction endotracheal tubes due to a design flaw that results in poor performance and complications.19 Single-port devices focus all suctioning through a single port that is pointed at airway tissue. In a one hour study, suction lumen dysfunction was confirmed in 48% of patients after an average of 6 minutes of operation.19

“Moreover it appears that the dominant cause of suction lumen dysfunction was occlusion of the subglottic suction port by suctioned tracheal mucosa (Fig 1). This finding raises significant questions concerning the safety of evacuation of subglottic secretions with subglottic suction using the Evac ETT” “The herniation of tracheal mucosa within the suction port, caused by the negative pressure, impedes local tissue perfusion, producing local tracheal mucosa ischemia”.19

![Endoscopic View of Suction Lumens](image)

**Figure 1.** The cause of suction lumen dysfunction. Schematic illustration of the prolapse of tracheal mucosa into the subglottic suction port. An endoscopic photograph of the subglottic suction port seen through the tracheal lumen in a case with suction lumen dysfunction is presented. (a) The blue radiopaque marker of the Evac endotracheal tube (ETT).

Other documented clinical complications due to this design flaw include tracheoesophageal fistula, dysphonia, transient dyspnea, and laryngeal edema.20,21,22 The poor efficacy combined with the risk of airway trauma and clinical complications have restricted the use of these devices to the ICU where vacuum pressure regulators allow for strict control of vacuum settings.
However, “A modification of the Evac ETT to keep the suction port away from the tracheal surface would probably eliminate suction lumen dysfunction”\textsuperscript{19}

**The Aspire Multi-port Endotracheal tube**
The Aspire is the only multi-port suction endotracheal tube. It utilizes a 24-port tissue spacer positioned directly above the cuff to drain subglottic fluids. The 24 suction ports have the same surface area of a single large suction port and the soft/smooth blue spacer suspends and directs all suctioning away from airway tissue. Ports are also located closer to where the secretions pool.

**Better Efficacy**
In an independent 48 hour experiment looking at the suction efficacy, the Aspire removed significantly more subglottic fluid when compared to the market leading single-port tubes.\textsuperscript{23} The NeVap Aspire has also demonstrated that it avoids mucosal injury and overcomes the difficulties of continuous suction encountered by single suction port endotracheal tubes.\textsuperscript{24}
**Expanded Use**

Due to design, the suction ports of the Aspire avoid contact with tracheal tissue. This has allowed the Aspire to be used in other settings where patients have a high risk of aspiration. Without additional capital equipment, expenditure, or significant clinical training, the Aspire is already being used in a select few US Operating Rooms and Emergency Departments to further prevent hospital acquired pulmonary infections that are, too often, antibiotic resistant in nature.

<table>
<thead>
<tr>
<th></th>
<th>Cost/device</th>
<th>ICU suction</th>
<th>OR suction</th>
<th>ED suction</th>
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<tbody>
<tr>
<td>NEVAP (Aspire)</td>
<td>$25-18</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Medtronic (Shiley)</td>
<td>$25-18</td>
<td>Y</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Avanos (Microcuff)</td>
<td>$25-17</td>
<td>Y</td>
<td>N</td>
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<tr>
<td>Teleflex (ISIS HVT)</td>
<td>$27-20</td>
<td>Y</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>CR BARD (Argento)</td>
<td>$120-100</td>
<td>N</td>
<td>N</td>
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**Safety Through Better Design**

The blue spacer is composed of a soft medical grade Polyvinylchloride (PVC) that is chemically welded to the PVC body of the tube in multiple places. This chemical weld requires forces in excess of 20lbs to remove the spacer and allows the appendage to withstand long-term exposure to low pH gastric secretions. The semi-circular shape ensures subglottic drainage is possible, even when the patient or the patient’s head is repositioned to one side.

A tertiary ambient air channel extruded into the wall of the Aspire also ensures that the airway does not collapse around the body of the endotracheal tube, during suctioning. This safety feature also ensures that the Aspire never appears blocked and that fluids will progress through the suctioning line. Respiratory and nursing care practitioners use less time confirming the patency of the suction on the Aspire, as any non-moving fluid will mean there is a problem.
**Additional Features**
The Aspire also features additional workflow and clinically helpful features that can further aid clinicians. The device is MRI safe, video laryngoscope stylet compatible, and conforms to airway anatomy at body temperature. Additionally, the Aspire has the following device features that help further support its clinical use and adoption.

<table>
<thead>
<tr>
<th>Product Information</th>
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<tbody>
<tr>
<td><strong>ID</strong>(mm)</td>
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<tr>
<td>6.5</td>
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<td>6.0</td>
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**Packaging**
Supplied Sterile, in single use pouches, in boxes of 10 tubes
Citations
February 16, 2018

NeVap, Inc.
℅ Janet Kwiatkowski
President
MAE Consulting Group, LLC
119 North Road
Deerfield, New Hampshire 03037

Re: K172208
Trade/Device Name: NeVap Aspire Subglottic Suction Endotracheal Tube (ASSET) with Preloaded Stylet
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: January 17, 2018
Received: January 18, 2018

Dear Janet Kwiatkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);
and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to [http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm) for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice ([https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/)) and CDRH Learn ([http://www.fda.gov/Training/CDRHLearn](http://www.fda.gov/Training/CDRHLearn)). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website ([http://www.fda.gov/DICE](http://www.fda.gov/DICE)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Investigating the Failure to Aspirate Subglottic Secretions with the Evac Endotracheal Tube

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George I. Vretzakis, MD, PhD†
Vassilios E. Papaioannou, MD, PhD*
Vassilios N. Didilis, MD, PhDD
Theodisia D. Vogiatzaki, MD, PhD§
Ioannis A. Pneumatikos, MD, PhD*

BACKGROUND: Aspiration of subglottic secretions is a widely used intervention for prevention of ventilator-associated pneumonia. However, using the Hi-Lo® Evac endotracheal tube (Hi-Lo Evac; Mallinckrodt; Athlone, Ireland) (Evac ETT), dysfunction of the suction lumen and subsequent failure to aspirate the subglottic secretions are common. Our objective in this study was to determine the causes of suction lumen dysfunction experienced with the Evac ETT.

METHODS: We studied 40 adult patients intubated with the Evac ETT. In all cases for which dysfunction of the suction lumen was observed, the subglottic suction port was examined visually using a flexible bronchoscope.

RESULTS: Dysfunction of the suction lumen occurred in 19 of 40 patients (48%). In 17 of these (43%), it was attributed to blockage of the subglottic suction port by suctioned tracheal mucosa.

CONCLUSION: Evacuation of subglottic secretions using the Evac ETT is often ineffective due to prolapse of tracheal mucosa into the subglottic suction port.

(Anesth Analg 2007;105:1083-5)

Aspiration of the secretions pooled immediately above the endotracheal tube cuff (subglottic space) is considered an important mechanism in the pathogenesis of ventilator-associated pneumonia (VAP). The Hi-Lo® Evac endotracheal tube (Hi-Lo Evac; Mallinckrodt; Athlone, Ireland) (Evac ETT), incorporating a separate suction port above the endotracheal tube cuff (subglottic space) is designed for evacuation of subglottic secretions. The Evac ETT suction lumen has two ports: a subglottic port located 15 mm above the cuff, with an elliptical shape (major axis 6 mm, minor axis 3 mm), and an external port for connection to suction. Clinical trials have shown that the evacuation of subglottic secretions using the Evac ETT (with continuous or intermittent suction) contributes to reduction in VAP rates (1–5), whereas several reviews and guidelines favor its use as a VAP preventive measure (6–9). However, Rello et al. reported failure to aspirate subglottic secretions using the Evac ETT with an incidence of 34% (28 of 83 patients), and considered the above mechanism as a risk factor for VAP development (5). Nevertheless, causes of Evac ETT aspiration failure have not been clearly identified. Therefore, we conducted a prospective observational study to investigate the incidence and possible causes of Evac ETT aspiration malfunction in 40 critically ill patients.

METHODS
Forty adult patients were enrolled in our study after approval by our Institutional Scientific Board. After orotracheal intubation with the Evac ETT (internal diameter 7–7.5 mm for women and 8–8.5 mm for men), confirmation of proper tube position with capnography, palpation of the cuff at the sternal notch, and lung auscultation, the tube was secured at right angle of the orifice of the mouth. The depth of insertion of the Evac ETT was 23 cm in men and 21 cm in women. The cuff was inflated to a pressure between 20 and 25 mm Hg.

After initial stabilization of the patients, we evaluated the Evac ETT suction lumen for dysfunction as follows: Sedated and paralyzed patients were placed in a 30 degrees semirecumbent position, with the head in a neutral position, and given ventilatory support. The suction lumen was connected to wall suction through a continuous suction regulator set at −15 mm Hg negative pressure via a 20-mL sputum trap, and 20 mL of water for injection was administered in the oral cavity. The pressures of the wall suction regulator and the sputum trap...
were observed for 60 min. Suction lumen dysfunction was defined as negative pressure in the manometer of the suction regulator below –20 mm Hg for 15 min with no evidence of secretions being suctioned. In cases where dysfunction was noted, the negative pressure of the wall suction was recorded, and the subglottic port of the suction lumen was evaluated visually via the ETT by two experienced intensivists at the same time, using a fiberoptic bronchoscope (Olympus ENF/P3, Tokyo, Japan). The blue radiopaque marker, placed between the subglottic suction port and the cuff, was used to identify the subglottic suction port (Fig. 1). For patients in whom the suction lumen dysfunctioned, the negative pressure to the suction port was discontinued definitively.

Ninety-five percent confidence intervals (95% CI) were calculated for the incidence and causes of suction lumen dysfunction.

RESULTS

The 40 patients studied (26 men/14 women) had a median (interquartile range; IQR) Acute Physiology and Chronic Health Evaluation II score of 15 (12–17), a median (IQR) age of 62.5 (47.5–73.7) years, a median (IQR) height of 1.69 (1.63–1.74) m, and a median (IQR) weight of 77.5 (66.7–80.7) kg.

The incidence of suction lumen dysfunction was 48% (19 of 40 patients), with a 95% CI: 32%–63%. Endoscopic examination attributed the ETT dysfunction to an obstruction of the subglottic suction port by suctioned tracheal mucosa in 17 of 40 patients (43%) (95% CI: 27%–58%) (Fig. 1). In one case, the subglottic suction port was occluded by thick secretions, and in another, the cause of the dysfunction was not identified because of a poor endoscopic image. In cases with suction lumen dysfunction the decrease of negative pressure started at a median time of 6 min (IQR: 4–16 min).

DISCUSSION

The observed incidence of Evac ETT suction lumen dysfunction in our study was high, 48% (95% CI: 32%–63%). Moreover, it appears that the dominant cause of suction lumen dysfunction was occlusion of the subglottic suction port by suctioned tracheal mucosa (Fig. 1). This finding raises significant questions concerning the safety of evacuation of subglottic secretions with subglottic suction using the Evac ETT. Negative pressure of less than –20 mm Hg favors prolapse of tracheal mucosa into the subglottic suction port. The herniation of tracheal mucosa within the suction port, caused by the negative pressure, impedes local tissue perfusion, producing local tracheal mucosa ischemia.

Our findings explain those of Bera et al., who found in an animal study that aspiration of subglottic secretions can cause severe tracheal injury in an area immediately adjacent to the subglottic suction port (10). Moreover, Girou et al. (11) considered the very high incidence (40%) of laryngeal edema in patients receiving subglottic suctioning as an adverse effect of continuous subglottic suctioning. The lower rate of aspiration failure reported by Rello et al., 34% (28 of 83 patients) (95% CI: 24%–45%), could be attributed to the lower sensitivity of their method for detection of subglottic suction port obstruction (5).

Orotracheal tubes are curved to facilitate intubation. This shape increases the possibility that the posterior surface of the tube, where Evac’s distal suction port lies, is close to or touches the trachea. A modification of the Evac ETT to keep the suction port away from the tracheal surface would probably eliminate suction lumen dysfunction.

In conclusion, evacuation of subglottic secretions with continuous low negative pressure subglottic aspiration using the Evac ETT is often ineffective due to the prolapse of tracheal mucosa into the subglottic suction port, and probably exposes the patient to a high risk of tracheal injury. Consequently, we suggest that aspiration of subglottic secretions with the Evac ETT for prevention of VAP be performed in conjunction with closed monitoring for dysfunction of the suction lumen and with discontinuance of suction when dysfunction occurs.

REFERENCES