COMMERCIALLY AVAILABLE

2022

Multiport suction breathing tube

Country of origin | United States of America
Primary function | Prevention
Category | Medical device

Commercial information

List price (USD): 18
Year of commercialization: 2019
Number of units distributed: 10,000-50,000
Currently marketed in: Globally
Brand: NeVap Inc
Model: Aspire Subglottic Suction Endotracheal Tube

Product description

The NeVap Aspire is the only suction breathing tube with a tissue spacer and 24 suction ports, which prevent tissue blockage and allow for effective, non-traumatic subglottic removal of pathogenic fluids that contribute to increased mechanical ventilation time, antibiotic use, ventilator-associated pneumonia, and mortality.

Product details

Facility requirements: Healthcare waste disposal facilities (medical waste), Gas supply (Oxygen and anesthetic gas) , Source of Ventilation and suctioning, Dry and cool storage

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NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In many resource-limited settings, lower respiratory tract infections, along with COVID-19 and respiratory diseases, are a major source of morbidity and mortality, ranking among the top 10 causes of death in low- and lower-middle-income countries. The COVID-19 pandemic has heightened the global demand for high-quality, safe, and affordable medical equipment to treat patients with respiratory failure, particularly those who require mechanical ventilation. The NeVap Inc multi-port subglottic suction endotracheal tube may offer a suitable solution for enhanced secretion removal in mechanically ventilated patients with respiratory failure, provided that the healthcare workforce receives appropriate, relevant training in its clinical use. The device's use may result in a lower risk of ventilator-associated pneumonia and a shorter period of stay in the intensive care unit.

WHO specification comparison

The "Aspire multiport suction breathing tube" has been compared with the "Endotracheal tube, with cuff" WHO technical specifications currently available in WHO publications. This device complies with the WHO technical specifications mentioned.

compliance: An endotracheal tube designed to maintain an unobstructed upper airway in order to transport gases and vapors to and from the lungs during anaesthesia, resuscitation, and other situations in which the patient is not properly ventilated. The Endotracheal Tube is designed with anatomical Magill Curve, Murphy Eye, and radiopaque markings. It includes a Pilot Balloon and inflation tube, a Cuff Balloon, a standard 15mm connector, and a preloaded "stylet." The cuff is inflated with a small-bore inflation tube that is included. The material is PVC. There are various sizes and lengths available. The Endotracheal Tube is individually packaged and sterile.

Non-compliance: None

Regulatory assessment

Pre-market assessment	Proceed with caution
Post-market assessment	Proceed with caution
Quality system assessment	Proceed with caution

The product has obtained CE marking. The USA FDA 510(k) clearance is only for the tracheal tube and removal of secretions claim and not the pneumonia prevention claimed in the labeling provided. PMS report has no date and data collected was only in 2018; the report itself is not robust. The post-market documentation should be provided to complete the assessment of this device.

They need to explain their relationship with Omnimate; CE Mark for Production QA & MDD expired April 2021 & ISO 13485:2003 expired Nov 2017; should have ISO 13485:2016.

Taiwan GMP certificate expired July 2019.

Animal study provided for COVID-19 claims; the report acknowledged that the suction at the end of the study was measuring higher than the original suction settings. This could be a patient safety issue and this was not discussed or justified in the report or with any corresponding risk analysis.

The 510(k) summary mentions several performance data reports but none were provided in this submission:

ISO 5361:2016, ISO 5356_1:2015, ISO 10993:2018, IEC 62366_1:2015,ISO 14971:2019, Suction Patency Test, Fluid Recovery Rates determination, Suction_T Pull Test (Shear and Tensile Force) and Isolated Suction_T Material Pull Test.

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact
Medical	→	→
Safety	→	→
Economy	!	!
Organizational	→	→
Legal	→	→
Social	!	!
Ethical	→	→
Green environment	✗	✗

This innovative device is used to remove accumulated subglottic secretion and pathogens. According to the documents submitted, its efficacy was demonstrated in randomized control trials as well as its effectiveness in up to 30,000 cases in three different countries and in low and middle-resource settings. Its use is simple, and because the device is integrated into the tube, no additional training on the process of endotracheal intubation is required. The device is only intended for single use. Even though the device has the potential to reduce healthcare costs, the price per unit in LMIC settings appears to be too high. This is an IP-protected product. There are no plans to produce on-site. However, given the medical benefits, a recommendation can be made.

Summary

Innovation		Technology evidence assessment	Recommended
Technology readiness level	9		

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	→	Ease of cleaning	N/A
Ease of Use	!	Ease of maintenance	N/A
Positive impact on clinical outcomes	!	Infrastructure requirements	!
Affordability	!	Local access to sales support	!
Engineering resources minimization	→	Local access to technical support	N/A
Cultural and social acceptability	N/A	Local access to training	N/A
Environmental conditions	→	Local access to spare parts	N/A
Aesthetics	!	Locations of use within target setting	!

Target settings: Secondary & Tertiary level

Airway support tube for mechanically ventilated patients that incorporates delivery of breathing gas, trachea suctioning, and visualization in an innovative way. It is reasonably priced. Clinical use training is correctly required due to the tissue sensitivity to the placement of the tube edge and pressurizing balloon inside the airway. This disposable product does not require the use of engineering resources or product maintenance.

Intellectual property and local production

Technology transferability	→
Openly access intellectual property	✗
Local production	✗

Intellectual property – It is patent-protected. To use this technology, authorization from the patent owner or the assignee is required.

Local production – For LMICs, the current product price is high and market demand is low. Currently, dedicated local production for only this product is not feasible. As demand grows, an existing LMIC manufacturer of the same product line can explore licensing options.

WHO related guidance material

- WHO Global Health Estimates (the top 10 causes of death) - https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death
- WHO Coronavirus (COVID-19) Dashboard - https://covid19.who.int/
- Coronavirus disease (COVID-19) technical guidance: Patient management - https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management
- Living guidance for clinical management of COVID-19 - https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2
- Therapeutics and COVID-19: living guideline - https://apps.who.int/iris/handle/10665/345356
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured - https://www.who.int/publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured
- Emergency Care - https://www.who.int/emergencycare/systems/en/
- Guidelines for essential trauma care - https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care
- Severe Acute Respiratory Infections Treatment Centre - https://www.who.int/publications/i/item/10665-331603
- Nosocomial pneumonia: risk factors, rates and trends - https://apps.who.int/iris/handle/10665/117465