

PneuX for preventing ventilator-associated pneumonia in intensive care

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Summary

The PneuX tube system is intended for airway management in critically ill patients who are having mechanical ventilation. It is designed to prevent ventilator-associated pneumonia by minimising the risk of pulmonary aspiration and micro-aspiration in patients having ventilation for 24 hours or more. One randomised controlled trial in high-risk cardiac patients found that the PneuX system was associated with a statistically significant reduction in the incidence of ventilator-associated pneumonia compared with a standard endotracheal tube. A PneuX endotracheal tube costs £150 and a PneuX tracheostomy tube costs £175 (both excluding VAT).

<p>Product summary and likely place in therapy</p> <ul style="list-style-type: none">• PneuX is a endotracheal/ tracheostomy tube system for airway management designed to prevent ventilator-associated pneumonia (VAP) in patients having ventilation for 24 hours or more.• The system could be used to replace standard endotracheal and tracheostomy tubes that have no subglottic drainage access, subglottic drainage access but with a high pressure cuff, or no continuous cuff-pressure monitor.	<p>Effectiveness and safety</p> <ul style="list-style-type: none">• One UK-based randomised controlled trial in 240 high-risk patients having cardiac surgery found that PneuX was associated with a significant reduction in VAP incidence compared with a standard endotracheal tube (10.8% compared with 21%, $p=0.03$). There was no statistically significant difference in any other outcome measures.• One UK-based retrospective cohort study in a medical and surgical ICU reported VAP incidence of 6% in 48 patients with the PneuX system. Unplanned extubation was reported in 17% of patients; 10% of patients self-extubated.• One UK-based retrospective cohort study in 53 critically ill patients with the PneuX system found no incidence of VAP while the PneuX system was in place.• One UK-based retrospective cohort study analysing records of 185 intubations using the PneuX system found that the incidence of unplanned extubations was 0.1% over 982 intubation days.
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Technical and patient factors	Cost and resource use
<ul style="list-style-type: none"> • The PneuX system consists of an endotracheal or tracheostomy tube, the PneuX tracheal seal monitor and an extension tube. The manufacturer recommends that the tube and monitor should only be used together and not with other devices. • The PneuX endotracheal/tracheostomy tube has multiple access ports for subglottic drainage and a low-volume, low pressure cuff made from soft silicone. The PneuX tracheal seal monitor has a default setting to maintain a constant low pressure on the tracheal wall (30 cm H₂O, which requires an intra-cuff pressure of 80 cm H₂O). • The PneuX endotracheal/tracheostomy tube is available in 3 sizes, with an inner diameter of 7.0, 8.0 or 9.0 mm. A smaller PneuX endotracheal tube with an inner diameter of 6.0 mm is also available. Both the PneuX endotracheal/tracheostomy tube and the extension tube are supplied sterile and for single use. 	<ul style="list-style-type: none"> • A single-use PneuX endotracheal tube costs £150 (excluding VAT). • A single-use PneuX tracheostomy tube costs £175 (excluding VAT). • The PneuX tracheal seal monitor is provided to the hospital on a loan basis. • The extension tube is provided at no charge to the hospital.

Introduction

Ventilator-associated pneumonia (VAP) is a hospital-acquired infection. Although there is no consensus definition, it is often defined as pneumonia that occurs in patients who have had intubation with an endotracheal or tracheostomy tube to help or control respiratory function continuously for at least 48 hours before the onset of the pneumonia (American Thoracic Society and Infectious Diseases Society of America, 2005). The presence of a tracheal tube interferes with the normal protective reflexes of the upper airway, such as coughing. This can result in impaired clearance of micro-organisms and rapid colonisation of the oropharyngeal secretions with aerobic Gram-negative bacteria. These contaminated secretions gather above the cuff of the tracheal tube

and slowly leak down into the airway, leading to the unintentional entry of very small amounts of contaminated material into the respiratory tract (micro-aspiration). This is the main cause of VAP (Hunter 2012). There are no standard criteria to diagnose VAP; a diagnosis is generally based on clinical signs and symptoms, chest X-rays and microbiological confirmation (American Thoracic Society and Infectious Diseases Society of America, 2005).

Around 83,500 intubations were carried out in England in 2013–14 (Health and Social Care Information Centre, 2015). Because of a lack of standardised diagnostic criteria, it is difficult to quantify the exact incidence of VAP. However, VAP is a common complication of mechanical ventilation and the most common infection in ICU (Bouza et al. 2006, Zuschneid et al. 2007, Hunter 2012). Between 10% and 20% of patients who have mechanical ventilation for longer than 48 hours will develop VAP. Critically ill patients who develop VAP appear to be twice as likely to die compared with similar patients without VAP (Safdar et al. 2005).

Risk factors for the development of VAP include prolonged mechanical ventilation, older age, lying face-up and comorbidities (Bauer et al. 2000). The risk for patients is highest during early ICU stay when it is estimated to be 3% per day during days 1–5 of ventilation, 2% per day during days 5–10 of ventilation and 1% per day thereafter (Masterton, 2008).

Various strategies have been developed to reduce the risk of ICU patients developing VAP, including specialised endotracheal tubes. These tubes include features for continuous subglottic drainage and adequate pressure of the endotracheal-tube cuff to prevent leakage of colonised subglottic secretions into the lower airway (Kollef, 1999; Dodek et al. 2004).

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The PneuX system consists of a class III device (endotracheal/tracheal tube) and a class IIb device (PneuX tracheal seal monitor, previously known as Venner tracheal seal monitor). The manufacturer, Venner Medical (Singapore) Pte, received a CE mark for the PneuX endotracheal and

tracheostomy tubes on 20 March 2007 and for the tracheal seal monitor and extension tube on 22 October 2007.

Description

The PneuX system was formerly known as the Venner PneuX P.Y. - VAP Prevention System and the Lo-Trach system. It has also been referred to as the PneuX VAP prevention system, the PneuX P.Y. system and the Venner-PneuX system. The system is designed to prevent VAP by minimising the risk of pulmonary aspiration and micro-aspiration during long-term mechanical ventilation, which is expected to be more than 24 hours but no more than 30 days.

The PneuX system consists of 3 component parts:

- PneuX endotracheal/tracheostomy tube – a flexible silicone tube with a cuff, a flange, a drain tube, an inflation tube, a reservoir and a 15 mm standard connector. The tubes are compatible with magnetic resonance imaging (MRI) and are available in 3 sizes: 7.0, 8.0 or 9.0 mm inner diameter. A smaller PneuX endotracheal tube with an inner diameter of 6.0 mm is also available.
- The PneuX tracheal seal monitor – an electronic automatic pressure controller for the inflation volume and pressure within the tube cuff during use.
- Extension tube – a 2-metre extension tube for the PneuX tracheal seal monitor. It connects the air outlet on the PneuX tracheal seal monitor and the pilot valve of the PneuX endotracheal/tracheostomy tube.

The system has the following main features:

- Low-volume, low-pressure cuff and PneuX tracheal seal monitor – the low volume cuff is made from a soft silicone material. The PneuX tracheal seal monitor is an electronic automatic pressure controller which controls and maintains the safe inflation volume and pressure within the cuff during use. Its default setting is to maintain a constant low pressure on the tracheal wall (30 cm H₂O), which is recognised to reduce the risk of tracheal mucosa injury compared with higher pressures. An intra-cuff pressure of approximately 80 cm H₂O is needed to produce a pressure of 30 cm H₂O on the tracheal wall. By continuously adjusting and maintaining the pressure of the cuff against the trachea wall, the monitor is designed to allow the cuff to produce a tracheal seal without creases, which the manufacturer claims is optimal for reducing the risk of aspiration. The cuff and monitor also allow for intermittent increases in

cuff pressure, allowing for safe airway irrigation. This is designed to reduce the risk of upper airway colonisation and to make it easier to remove detritus from the oropharynx.

- Wire-reinforced tube – the PneuX endotracheal/tracheostomy tube is a soft silicone wire-reinforced tube, which conforms to the anatomy and requires a bougie for intubation.
- Non-stick coating of the inner lumen – the non-stick lining reduces the risk of biofilm formation.
- Boat tip – the tip of the PneuX endotracheal/tracheostomy tube is bevelled with a Murphy eye (an additional hole at the tip) to aid the tube's passage into the trachea. This is intended to allow atraumatic intubation and optimum adaptation to the airway.
- Three suction ports – there are 3 subglottic secretion drainage and irrigation ports above the proximal end of the cuff to allow the tube to function properly even if a port is blocked. The small size of the subglottic ports is intended to prevent damage to the tracheal mucosa.

The manufacturer recommends that the PneuX endotracheal/tracheostomy tube and the PneuX tracheal seal monitor are used together, and so neither should be used with other devices.

Setting and intended use

The PneuX system can be used in intensive or critical care patients having mechanical ventilation, particularly in cases where the duration of intubation is expected to be more than 24 hours (but not more than 30 days). The PneuX system is also compatible with tracheal intubation during routine anaesthesia. It can be placed by anaesthetists and maintained by critical care nurses.

Current NHS options

VAP prevention strategies vary considerably in current practice.

In 2008, the Working Party on Hospital-Acquired Pneumonia of the British Society for Antimicrobial Chemotherapy produced evidence-based guidance (Masterton et al. 2008). The scope of the guidance excluded oral antiseptic treatments, severely immunocompromised patients, children under 16 years old and people with cystic fibrosis. The guidance states that measures should be taken to prevent VAP by reducing aspiration via subglottic secretion drainage, correct positioning of the tube and sufficient cuff pressure to avoid aspiration and tracheal damage.

The Patient Safety First [How to Guide for critical care](#) (2008) provides advice on mechanical ventilation and the NHS ventilator care bundle.

The NHS ventilator care bundle has 4 key components:

- elevation of the head of the bed to between 30 and 45 degrees
- daily sedative interruption and daily assessment of readiness to extubate
- peptic ulcer disease prophylaxis and venous thromboembolism prophylaxis
- appropriate humidification of inspired gas and appropriate tubing management.

The guide recommends that centres should monitor care bundle compliance and patient outcomes in order to assess the efficacy of this approach. These measurements include:

- ventilator care bundle compliance, by determining the percentage of patients having all 4 components of the care bundle
- cumulative count of the number of days that have passed without VAP being reported
- average length of stay on mechanical ventilation
- average length of stay in ICU
- VAP rate per 1000 ventilator days.

Subglottic secretion drainage/suctioning is not included in the care bundle, because the bundle is intended to offer solutions that are rapidly and readily available to hospitals. However, the guide states that subglottic suctioning is an effective therapy for reducing VAP rates and that if an ICU has experience of doing the procedure it should continue to offer it.

The guide also states that although the bundle has omitted some interventions, the selection of a few well-established measures serves to minimise risks to the patient. It also states that proper use of the ventilator bundle leads to near zero rates of VAP over prolonged periods of time.

The Scottish Intensive Care Society/Health Protection Scotland [VAP prevention bundle – Guidance for implementation](#) recommends 5 key elements to be addressed together to minimise the risk of VAP: sedation, weaning and extubation, patient positioning, oral antiseptics and subglottic secretion drainage. Of these the PneuX system would specifically address the last point, subglottic secretion drainage.

In 2011, the National Resource for Infection Control published [High impact intervention No.5: Care bundle to reduce ventilation-associated pneumonia](#). It outlined 6 key ways to prevent VAP.

These relate to patient positioning, sedation level, oral hygiene, subglottic aspiration, tracheal tube cuff pressure and stress ulcer prophylaxis. It recommends secretion drainage through the subglottic secretion port every 1–2 hours and cuff pressure measurements every 4 hours to maintain a pressure of 20–30 cm H₂O. The PneuX system with the wall seal pressure maintained at approximately 30 cm H₂O would specifically address the recommendation of subglottic aspiration drainage.

Overall, the various guidelines recommend the use of prophylactic antimicrobials, care bundles and patient positioning. Measures that are both specific to intubation tube selection and design and common to the various guidelines are secretion drainage through subglottic ports and sufficient cuff pressure to avoid aspiration and tracheal damage. The PneuX system includes both those features.

NICE is aware of other CE-marked devices that appear to fulfil a similar function to the PneuX system. Examples include:

- Microcuff endotracheal tube (Kimberly-Clark)
- Mallinckrodt Evac oral tracheal tube Seal Guard, Murphy Eye (Covidien)
- Mallinckrodt Seal Guard (Covidien)
- TaperGuard Evac oral tracheal tube (Covidien)
- UnoFlex reinforced endotracheal tube (ConvaTec).

Costs and use of the technology

The PneuX system has the following costs (unit price, exclusive of VAT and carriage):

- Endotracheal tube (size of 7.0, 8.0 or 9.0 mm inner diameter; MRI-compatible): £150
- Tracheostomy tube (size of 7.0, 8.0, or 9.0 mm inner diameter; MRI-compatible): £175
- Tracheal seal monitor: provided on loan basis to the hospital
- Extension tube: provided at no charge to the hospital.

The PneuX endotracheal/tracheostomy tube and the extension tube are sterile and for single patient use. The shelf life for the PneuX endotracheal/tracheostomy tube is 2 years. The tubes are packed as single units and supplied as a box of 10 units of a single size. The extension tube is

available separately. The manufacturer provides a comprehensive training programme at no additional cost to the hospital/trust. There are no maintenance or calibration requirements for the system and the PneuX tracheal seal monitor is serviced at 2-year intervals by the manufacturer at no additional cost.

In the NHS, the standard intubation tube (and their cost) varies from department to department. A number of example standard tubes and their costs is shown below (price of each tube exclusive of VAT; supplied in a box of 10 tubes):

With subglottic suction:

- Smiths Medical Portex oral endotracheal tube cuffed with Murphy eye and SACETT suction above cuff (inner diameter 7.0 mm, outer diameter 10.4 mm): £7.80
- Covidien TaperGuard EVAC Tracheal standard endotracheal tube, cuffed with Murphy eye (inner diameter 7.0 mm, outer diameter 9.5 mm): £11.60
- PROACT PRO-Breathe standard endotracheal Tube, cuffed with Murphy eye evacuation lumen (inner diameter 7.0 mm): £3.25.

Without subglottic suction:

- Smiths Medical Portex standard endotracheal tube cuffed with Murphy eye, clear low-pressure cuff (inner diameter 7.0 mm): £1.35
- PROACT PRO-Breathe standard endotracheal tube, cuffed with Murphy eye oral/nasal PVC low-profile cuff (inner diameter 7.0 mm): £1.12.

Likely place in therapy

The PneuX system would be used in place of standard endotracheal or tracheostomy tubes which have no subglottic access, subglottic access but with a high-pressure cuff, or no continuous cuff-pressure monitor, during long-term intubation (which is expected to be more than 24 hours but no more than 30 days).

Specialist commentator comments

One specialist commentator considered that maintaining a constant cuff pressure is a very beneficial feature of the PneuX system, and that continuous cuff-pressure monitoring should further reduce the risk of micro-aspiration. At present, in their ICUs, cuff pressure is measured

once per nursing shift (that is, once every 8 hours) and there is a tendency for cuff pressure to fall during this time.

One specialist commentator was concerned that there may be some difficulties in predicting which patients will be intubated for more than 24–48 hours, which could lead to an increased risk of having to change the endotracheal tube. Reintubation may cause a problem for some patients, particularly those with severe burns and swollen airways in whom it would not be advisable to change a tube.

A specialist commentator noted that the smaller PneuX endotracheal/tracheostomy tubes have a significantly larger external diameter than comparable tubes. For example, the PneuX endotracheal/tracheostomy tube with an inner diameter of 6.0 mm has an outer diameter of 9.9 mm, compared with 9.0 mm for other endotracheal tubes. This may lead to difficulties during tube changes if the anaesthetist is not aware of the difference.

Another specialist commentator thought that the PneuX system may assist critical care nurses and doctors in reducing incidences of VAP, but that more robust research needs to be done.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Risk factors for VAP include age (incidence increases with advancing age) and chronic illnesses (underlying chronic lung disease), which may significantly affect activities of daily living to the point where a person can be considered to be disabled. Age and disability are protected characteristics under the Equality Act (2010).

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website for manufacturer Field Safety Notices or Medical Device Alerts for this device revealed one advisory notice issued on 12 October 2010. The notice reported that, in an isolated incident, a LoTrach (that is, PneuX) tracheostomy tube migrated through its locking mechanism, which resulted in the loss of the patient's airway. It was stated that LoTrach tracheostomy tubes and endotracheal tubes of all sizes were potentially affected. The patient was re-intubated and suffered no long-term harm. No component failures were identified. No reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

A literature search identified 3 published studies relevant to this briefing; 1 was a randomised controlled trial (Gopal et al. 2015) and 2 were retrospective cohort studies (Smith et al. 2014; Doyle et al. 2011). They are summarised in [tables 1 to 6](#) of this briefing.

One study published as an abstract only was also identified to be relevant (Hodd et al. 2009). The study is summarised in [table 7](#).

Four conference abstracts were also identified, 1 (Gopal et al. 2013) reporting the published Gopal et al. (2015) study, 1 (Smith et al. 2011) reporting the published Smith et al. (2014) study and 2 (Carter et al. 2009; Fletcher et al. 2009) reporting data from the published study by Doyle et al. (2011). None of the abstracts provided any additional information to the published papers, and so they were not summarised in the briefing.

One study, published as an abstract only (Crommett et al. 2013), used the PneuX system in 39 critically ill patients. The only outcome measured was the amount of secretions on the inner lumen of the PneuX endotracheal/tracheostomy tube. This study was not included in this briefing because it did not report patient outcomes.

The trial by Gopal et al. (2015) was a UK-based, single-centre randomised controlled trial comparing the PneuX system with a standard endotracheal tube in high-risk adults having cardiac surgery. Each intubation group comprised 120 patients and the follow-up period was 48 hours after

extubation. The primary outcome measure was the incidence of VAP, confirmed using the [Hospitals in Europe Link for Infection Control through Surveillance](#) definition.

VAP incidence was significantly lower in the PneuX group than in the standard group (10.8% compared with 21%, $p=0.03$). The between-group difference with 95% confidence intervals (CI) was not reported in the paper. These data were used to calculate an absolute risk difference of 10% (95% CI 1% to 19%), which equates to a number needed to treat of 10 (95% CI 5.3 to 100.0). There was no significant difference between the 2 groups in terms of length of ICU stay ($p=0.2$) and in-hospital mortality ($p=0.2$). There were also no statistically significant differences between the 2 groups in terms of re-exploration rates, intubation duration and cardiopulmonary bypass duration.

Smith et al. (2014) reported on a retrospective cohort study in an ICU in an NHS hospital trust, which included 48 patients who were intubated with the PneuX system during 2010. The follow-up period was not specified but the primary outcome was incidence of VAP. The diagnosis of VAP was based on the recommendations of the American Thoracic Society and the Infectious Diseases Society of America 2005.

Three of the 48 patients in the study developed VAP (6.25%, 95% CI 1.3% to 17%). In these 3 patients, VAP was first identified on days 3, 7 and 9 after intubation. There was a 17% incidence of unplanned extubation, of which 5 incidents (10%) were classed as self-extubation. The authors concluded that, compared with other published studies, there appeared to be a higher rate of unplanned extubations, mostly self-extubations, raising concerns about patient safety. They suggested that further trials would be needed to determine the value of the system in clinical practice.

The study by Doyle et al. (2011) was a retrospective cohort study in a general ICU at a NHS hospital trust, which analysed 53 critically ill patients who sequentially were intubated with the PneuX system over 14 months. The primary outcome was incidence of VAP but the follow-up period was not specified. VAP was diagnosed based on clinical suspicion, international consensus criteria or clinical pulmonary infection score. There were no VAP episodes while the PneuX endotracheal tube was in place. One patient needed re-intubation following elective extubation, and developed VAP 2 days later while the conventional tube was in place. This gave a VAP rate in the 53 patients of 1.8%.

The abstract by Hodd et al. (2009) reported a retrospective cohort study in an ICU at a NHS hospital trust. The electronic medical records of all ICU patients intubated with the PneuX system over 2006–09 (185 intubations) were analysed. The primary outcome was the incidence of

unplanned extubations. There was 1 unplanned extubation (self-extubation) during that period, resulting in an incidence of 0.1% (1.02 unplanned extubations per 1000 intubation days).

Recent and ongoing studies

No ongoing or in-development trials on the PneuX system for patients in ICU at risk of VAP were identified.

Costs and resource consequences

No published evidence was identified on the direct costs and resource consequences related to using the PneuX system in preventing VAP. If the PneuX system reduced the incidence of VAP, then resources related to the treatment of VAP and VAP-related emergency department, ICU and hospital stay could be saved. According to the manufacturer, 3 NHS hospitals are currently using the PneuX system.

One abstract (Carter et al. 2009) reported the same data as the published paper by Doyle et al. (2011). No cases of VAP were seen in the 58 patients with the PneuX system in place. On an intention-to-treat basis the VAP rate was 1.8%, because 1 patient who needed reintubation with a conventional endotracheal tube developed VAP while the tube was in place. With a 10–20% expected incidence of VAP, the authors extrapolated that 5–10 episodes of VAP were expected in this study.

The authors stated that the price of the PneuX system was \$250 (approximately £160) per patient, making a total cost per year of \$11,400 (approximately £7480) in their institution; for comparison, other researchers have estimated that treating a single case of VAP costs around \$10,019 (approximately £6490).

Gopal et al. (2015) cited a review paper that puts the cost of VAP treatment in the USA at around \$40,000 (approximately £25,900) per patient. The authors then stated that in their study, there were 12 fewer patients with VAP in the PneuX group than in the standard endotracheal tube group. This was equal to a potential cost saving of \$480,000 (approximately £310,750). The authors estimated that, assuming using PneuX costs \$100 (approximately £65) per patient, about 4800 patients could have been intubated using the PneuX system with at least a halving of the VAP rate. The cost of the PneuX system assumed by the authors is considerably lower than the current list price, so these results should be interpreted with caution.

Strengths and limitations of the evidence

The evidence is based on 3 published studies and 1 study available as an abstract.

The VAP diagnosis criteria used varied across the studies where the incidence of VAP was assessed. The follow-up period was reported in only 1 study (Gopal et al. 2015).

The Gopal et al. (2015) study was a single-centre randomised controlled trial. The trial may have been subject to a number of known sources of potential bias. The treatment assignment method using a computer-generated randomisation software program was appropriate, but it was unclear whether the random allocation of the treatments was concealed. A sample size calculation was done and the recruited number of patients in each group was sufficient. However, it was unclear whether a blinding method was applied to the treatments, for example to blind the outcome assessors, or those who analysed the data. Performance bias was minimised because other than the treatments being compared, patients in both groups received the same care, with both groups having routine respiratory care in the ICU as per the NHS ventilator care bundle and the same routine gastric stress ulcer prophylaxis. The patients included in this study were high-risk patients (over 70 years old or with impaired left ventricular ejection fraction of less than 50%) having elective and urgent cardiac surgery. This patient group may not be fully representative, being a specific subgroup of the patient population for whom the use of the PneuX system is intended. Because this was a single and relatively small study, the estimates of the effectiveness of the PneuX system are imprecise.

In the study by Smith et al. (2014) the patients were recruited using consecutive sampling, because it included all patients who met the inclusion criteria during the study period. In the study by Doyle et al. (2011) inclusions were sequential patients who had the PneuX system for mechanical ventilation during the study period. However, because both studies had a non-comparative single-cohort, the observed VAP rate with the PneuX system was not compared to that with an alternative tube. As such, conclusions regarding the comparative effectiveness of the PneuX system cannot be drawn from these studies.

One study published as an abstract only (Hodd et al. 2009) provided limited information in terms of study methods, characteristics and results, making it hard to judge the quality of the evidence in the abstracts.

All 4 studies were UK-based. Their results are likely to be generalisable to the UK healthcare settings.

Three authors of the Gopal et al. (2015) study received a grant from the distributor of the PneuX system to present the data following the completion of the study. The PneuX system used in the Smith et al. (2014) study was provided by the manufacturer. In the Doyle et al. (2011) study, 1 author is the inventor of the PneuX system and is a minor shareholder in the intellectual property ownership of the PneuX system and tracheal seal monitor. In the past this author received funding and consultancy fees from the manufacturer.

Relevance to NICE guidance programmes

The use of the PneuX system is not currently planned into any NICE guidance programme.

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Search strategy and evidence selection

Search strategy

1. The following databases were searched from inception to July 2015 using the keyword "Pneux", "LoTrach", and "Lo Trach": Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R); Embase (via OVID); Cochrane Library; CAB Abstracts; Web of Science Science Citation Index.

These citations were sifted through to identify any relevant material, using the inclusion criteria in the 'Evidence selection' section below.

2. The internet was searched using the above keywords.

3. ClinicalTrials.gov, WHO ICTRP, and Current Controlled Trials were also searched for ongoing trials.

4. Information provided by the manufacturer in supporting this briefing was checked to identify any further information.

5. The manufacturer's website was thoroughly investigated.

6. Information provided by the manufacturer was thoroughly checked for relevant studies.

Evidence selection

The inclusion criteria were as follows:

Population: adult cardiac patients requiring ventilation in a critical care setting who are at high risk of developing ventilator-associated pneumonia (VAP).

Intervention: the PneuX system, used for the prevention of ventilator-associated pneumonia. It was formerly known as the Venner PneuX P.Y. - VAP Prevention System and the Lo-Trach system. It has also been referred as the PneuX VAP prevention system, the PneuX P.Y. system, and the Venner-PneuX system.

Comparator: any other equivalent or similar technology aimed at VAP prevention, or conventional endotracheal or tracheal intubation tube.

Outcomes: any clinical efficacy and safety outcomes, including but not limited to:

- incidence of VAP
- length of ICU/ITU stay
- length of hospital stay
- incidence of secondary infection
- incidence of aspiration
- duration of mechanical ventilation
- antibiotic usage
- mortality
- adverse events
- cost savings.

Study type: published randomised or non-randomised controlled trials; published cohort studies. For safety aspect of the device published case report studies were included. Proof-of-concept, bench-top or basic science studies were excluded.

Non-English language studies were excluded.

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Table 1 Overview of the Gopal et al. (2015) study

Study component	Description
Objectives/ hypotheses	To assess whether the PneuX system is associated with a reduction in VAP when compared with the standard ET tube in high-risk patients undergoing cardiac surgery.
Study design	Single centre, randomised controlled trial comparing the PneuX tube with the standard tube. Follow-up period: 48 hours after extubation. Intermittent subglottic suctioning was performed at 6-hourly intervals.
Setting	Department of Cardiothoracic Surgery, Heart and Lung Centre, Wolverhampton, UK. Patients were transferred to the ICU post-operatively.
Inclusion/ exclusion criteria	Inclusion criteria: patients over the age of 70 years or with impaired LVEF (<50%) undergoing elective and urgent cardiac surgery. Patients who were recruited to other studies were excluded.
Primary outcomes	Incidence of VAP. A diagnosis of VAP was confirmed via the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) definition.
Statistical methods	Power calculations suggested ≥ 107 patients per group (power of 0.9 and an alpha of 0.01).
Patients included	High-risk patients undergoing cardiac surgery; n=240 (120 in each group).
Results	VAP incidence was significantly lower in the PneuX tube group than in the standard ET group (10.8% compared with 21%, p=0.03). ^a There was no significant difference between the two groups in terms of intensive care unit stay (p=0.2) and in-hospital mortality (p=0.2).

Conclusions	The PneuX system is associated with a significant reduction in VAP. This can potentially lead to significant cost reductions and should be implemented as part of the VAP reduction bundle.
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Abbreviations: CI, confidence interval; ET, endotracheal; ICU, intensive care unit; LVEF, left ventricular ejection fraction; n, number of patients; VAP, ventilator-associated pneumonia.

^a The between-group difference with 95% CI was not reported in the paper. The External Assessment Centre (principal authors of the briefing) used the presented data to calculate a risk difference of 10% (95% CI 1 to 19%) which equates to a number needed to treat of 10 (95% CI 5.3 to 100).

Table 2 Summary of results from the Gopal et al. (2015) study

	PneuX tube	Standard tube	Analysis
Randomised	n=120	n=120	
Efficacy	n=120	n=120	
Primary outcome: VAP incidence (n;%) ^a	13 (11%)	25 (21%)	p=0.03
Selected secondary outcomes:			
VAP incidence density ^b	52	184	<0.01
Survival	98%	99%	p=0.2
Median ICU stay (days)	2	1.5	p=0.2
Re-exploration (n;%)	17 (14%)	10 (8%)	p=0.2
Median intubation time (hours)	15	13	p=0.5

Mean CPB time (minutes±SD)	110±58	105±62	p=0.3
Mortality (n; %) ^c	2 (1.6%)	1 (0.8%)	p=0.2
Safety	The anaesthetists reported no difficulties in intubating patients with the PneuX tube. There was no accidental tube displacement or dislodgement. There was 1 case of a patient experiencing oxygen desaturation following suctioning and irrigation, which resulted in a transient increase in oxygen requirement. The patient was subsequently extubated uneventfully 12 hours later. An independent clinician from an external organisation was asked to comment on whether the patient had potentially aspirated the sterile water during the reported episode. The conclusion was that it was impossible to state with any certainty that the patient had aspirated the sterile water during the period of suction and irrigation. There were no reports of failure of the continuous cuff-pressure monitoring device.		
<p>Abbreviations: CPB, cardiopulmonary bypass; ET, endotracheal tube; EuroSCORE, European system for cardiac operative risk evaluation; ICU, intensive care unit; LVEF, left ventricular ejection fraction; n, number of patients; NR, not reported; SD, standard deviation; VAP, ventilator-associated pneumonia.</p> <p>^aThe between-group difference with 95% CI was not reported in the paper. The External Assessment Centre (principal authors of the briefing) used the presented data to calculate a risk difference of 10% (95%CI 1 to 19%) which equates to a number needed to treat of 10 (95%CI 5.3 to 100).</p> <p>^bNumber of VAP episodes per 1000 ventilator days.</p> <p>^cNone of the 3 patients who died had VAP.</p>			

Table 3 Overview of the Smith et al. (2014) study

Study component	Description
Objectives/hypotheses	To review the impact of the PneuX system on the incidence of VAP and its effects on local practice.
Study design	Retrospective cohort study. Follow-up period: not reported.

Setting	A mixed medical and surgical ICU, Hull and East Yorkshire Hospitals NHS Trust, in 2010.
Inclusion/exclusion criteria	All patients were intubated with the PneuX system and received its associated care package in the intensive care department during 2010. Identified using both paper and electronic hospital records.
Primary outcomes	Incidence of VAP. Diagnosis of VAP was based on the recommendations of the American Thoracic Society and the Infectious Diseases Society of America. ^a Clinical diagnosis of VAP was made if new radiographic infiltrates were present on a chest X-ray at 48 hours after initial intubation, in combination with at least 2 of the following: fever, leukocytosis, or purulent trachea-bronchial secretions.
Statistical methods	Not specified. Median (range) was used for the duration of the PneuX system being in place. 95% CI was reported for VAP incidence. The incidence of VAPs/1000 bed days was calculated based on the cumulative total of PneuX system use and the occurrence of VAP.
Results	Three of the 48 patients developed VAP (6.25%, 95% CI 1.3–17%). Two more cases of VAP were excluded due to pre-existing VAP.
Conclusions	The PneuX system facilitated lower VAP rates than those documented elsewhere and highlighted the incidence of unplanned extubations in local practice. Further evaluation of the implementation of the PneuX system in intensive care areas, in tandem with large-scale evaluation of its effectiveness, are still required.
<p>Abbreviations: CI, confidence interval; ICU, intensive care unit; VAP, ventilator-associated pneumonia.</p> <p>^a VAP as diagnosed by the ATS/IDSA guidelines (American Thoracic Society; Infectious Diseases Society of America. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. <i>American Journal of Respiratory and Critical Care Medicine</i> (2005) 171: 388–416.</p>	

Table 4 Summary of results from the Smith et al. (2014) study

Patients included	<p>Forty eight adult patients who were expected to be intubated for at least 24 hours, including 14 who had primary intubation with the PneuX system and 34 who underwent tracheal tube exchange to the PneuX system.</p> <p>Mean age 57.5 years.</p> <p>56% male.</p> <p>Type of patient: 32 medical, 7 surgical and 9 neurosurgical.</p>
Primary outcomes	<p>Three of the 48 patients developed VAP (6.25%, 95% CI 1.3–17%); 2 more cases of VAP were excluded due to pre-existing pneumonia.</p> <p>Of the 3 patients who were diagnosed with VAP, the onset of VAP was identified on days 3, 7 and 9 after initial intubation.</p>
Safety	<p>The majority of extubations were planned in advance but 17% (n=8) were classified as unplanned, with a majority (62%, n=5) of these being unplanned self-extubations. Patient self-extubation occurred in 13% (n=6) of the 48 patients.^a</p> <p>Physiotherapists commented that the tracheal tube felt 'too long,' which prevented suction catheters entering the trachea sufficiently to provide adequate suction.</p> <p>Some staff felt that while the bite block and lock nut secured the tube in the right position, it also acted as a grip for patients to achieve unplanned self-extubation.</p>

Abbreviations: CI, confidence interval; ICU, intensive care unit; VAP, ventilator-associated pneumonia; n, number of patients.

^aThe paper stated that "the majority (66%) of extubations were planned. However, of the remaining unplanned extubations, two were deemed to be accidental, where the patient was not responsible for tracheal tube removal, and 5 were classed as self-extubation. In a single case the tracheal tube was removed for clinical reasons". There are some discrepancies regarding the reported extubation rates.

Table 5 Overview of the Doyle et al. (2011) study

Study component	Description
Objectives/hypotheses	To determine the incidence of VAP in patients who were intubated with the PneuX system and to establish whether intermittent subglottic secretion drainage could be performed reliably and safely using the PneuX system.

Study design	Retrospective cohort study. Follow-up period: not reported.
Setting	At a Queen Elizabeth Hospital, NHS Trust. Follow-up period unclear.
Inclusion/exclusion criteria	Sequential critically ill patients aged more than 18 years who received the PneuX tracheal tube and cuff pressure controller for mechanical ventilation during a 14-month period in that hospital. The use of the PneuX system was restricted to those patients who were anticipated to require more than 24 hours of intubation.
Primary outcomes	Incidence of VAP. VAP was defined as any pneumonia that occurred after more than 48 hours of intubation and mechanical ventilation with the PneuX system. It was diagnosed by (i) clinical suspicion (including the use of any antibiotics for the treatment of colonisation or infection within the tracheobronchial tree or lungs); and/or (ii) international consensus criteria: the presence of new, persistent pulmonary infiltrates not otherwise explained, appearing on chest radiographs and at least two of the following criteria: temperature of greater than 38 degrees Centigrade; leukocytosis of greater than 10,000 cells/mm ³ and purulent respiratory secretions; or (iii) clinical pulmonary infection score (a fall in the PaO ₂ /FiO ₂ ratio of greater than 25% and a clinical pulmonary infection score of greater than 5 in the presence of bacteria in a qualitative endotracheal aspirate).
Statistical methods	Not specified.
Conclusions	The study demonstrates that a low incidence of VAP is possible using the PneuX system. It also demonstrates that elective exchange and intermittent subglottic secretion drainage can be performed reliably and safely using the PneuX system.
Abbreviations: ICU, intensive care unit; VAP, ventilator-associated pneumonia.	

Table 6 Summary of results from the Doyle et al. (2011) study

Patients included	Fifty-three critically ill patients aged older than 18 years received the PneuX system. All patients included in the study were intubated with the PneuX system and received mechanical ventilation for more than 48 hours. No patients intubated with the PneuX system were excluded from the analysis.
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Primary outcomes	<p>There were a total of 306 days of intubation with a mean of 5.3 days (range 1–18 days).</p> <p>Forty-four (83%) patients underwent a tube exchange and 17% were primary intubations with the PneuX system on the ICU.</p> <p>There were no episodes of VAP while the PneuX system was in situ.</p> <p>On an ITT basis there was a 1.8% VAP rate as 1 patient, who required reintubation following elective extubation, received a conventional tube and developed a VAP 2 days later with the conventional tube in situ.</p> <p>No antimicrobial therapy was initiated for chest infections in patients intubated with the PneuX system.</p>
Safety	<p>There were no complications from, or failure of, subglottic secretion drainage during the study.</p>
<p>Abbreviations: ICU, intensive care unit; ITT, intention to treat; VAP, ventilator-associated pneumonia.</p>	

Table 7 Summary of data from the Hodd et al. (2009) abstract

Objectives/hypotheses	<p>To determine the incidence of unplanned extubations using the PneuX system and to compare this with previously reported data. Hypothesis: the incidence of unplanned extubation is decreased when using the PneuX system compared to historical data.</p>
Study design	<p>Retrospective cohort study – analysis of the electronic medical records of ICU patients intubated with the PneuX system.</p>
Setting	<p>At a Queen Elizabeth Hospital, NHS Trust, during the period 2006–2009. Follow-up period unclear.</p>
Inclusion/exclusion criteria	<p>The electronic medical records of all ICU patients intubated with the PneuX system from 2006–2009 in the hospital.</p>
Primary outcomes	<p>Incidence of unplanned extubation.</p>
Statistical methods	<p>Not specified.</p>

Patients included	A total of 185 intubations with the PneuX system. No further information on the population.
Results	<p>During the 3-year period there were a total of 185 intubations with the PneuX system and 982 intubation days (mean 5.31, median 4).</p> <p>There was 1 unplanned extubation (self-extubation) during that period. This resulted in an incidence for unplanned extubations of 0.1% (1.02 per 1000 intubation days).</p>
Conclusions	The results suggest that the PneuX system compares favourably with figures reported in largest published database (7.6% incidence of unplanned extubation; 9.4 per 1000 intubation days). Engineered efforts to minimise unplanned extubation should be encouraged.
Abbreviations: ICU, intensive care unit; VAP, ventilator-associated pneumonia.	

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and are **not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by The Birmingham and Brunel Consortium. The [interim process & methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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Declarations of interest

No relevant interests declared.

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