

Venner PneuX[™] System

Engineered to protect with a multi-factorial approach

Prevents microaspiration past the tracheal tube cuff

Maintains the cuff seal during patient or equipment movement

Automates tracheal tube cuff pressure control

Permits Subglottic Secretion Drainage and irrigation

A need for change

Within **shared decision-making**, we need to address how Ventilator-associated Pneumonia (VAP) can impact a patient, their family and how this can be prevented with a system engineered to protect your patient.

"Ventilator-associated Pneumonia occurs in a considerable proportion of patients undergoing mechanical ventilation and is associated with substantial morbidity, a two-fold mortality rate, and excess cost. Given these findings, strategies that effectively prevent VAP are urgently needed." ³⁸ "...anyone admitted to a critical care area with a tracheostomy is likely to benefit from active humidification with a closed or open system." (Intensive Care Society, 2020)

"A tube with a cuff can keep some secretions or aspirated material out of the airways that would otherwise enter the lungs." (Intensive Care Society, 2020) 100% of patients in the East of England Citizens Senate in 2015, considered Venner PneuX[™] System an effective choice for their benefit, safety and highest chance of recovery. ⁴² "Our patients assume safe care and expect high quality care." (Intensive Care Society, 2020)

Deaths due to drug resistant infections in 30 years' time will outnumber the current number of deaths from cancer ³³

"Equipment should include ... a system or device to measure or monitor cuff pressure." (Intensive Care Society, 2020)

Healthcare Acquired Infections (HAIs)²⁷

£1 billion

Annual cost to NHS ²⁹ ²⁰

300,000

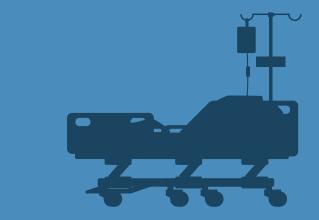
Cases per annum

≥20%

Avoidable

45.3% of HAIs in the ICU are made up of VAP and RTIs ²⁸

27% of antimicrobial use (excluding for prophylaxis) in hospital is prescribed for the treatment of HAIs ²⁸



Ventilator-associated Pneumonia (VAP)



£100 million

Annual cost to NHS

100,000

Patients admitted per annum for mechanical ventilation

10-20%

of patients will develop VAP ³⁸

3,000 to 6,000

Patients will die from VAP

£10,000 – £20,000 Cost per patient ^{26 20}

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Venner PneuX[™] System: Economics

"The Venner 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." ¹²

"Venner PneuX[™] is cost saving compared with standard care. The estimated total net savings for a hospital performing 300 episodes of intubation per year were £255,108. Return on investment (ROI): 668%."²⁷

"Overall, findings suggest that the benefits of Venner PneuX[™] exceed its additional cost, resulting in a total net benefit of £738 per patient. Venner PneuX[™] resulted in lower costs and a gain in quality-adjusted life years. The results are robust to extreme values of the key parameters in the analysis." ²



Causes of VAP and the tracheal tube

Ventilator-associated Pneumonia (VAP) continues to be a major cause of morbidity and mortality and excess cost in critically ill patients." ¹⁸

"Subglottic secretions may accumulate above the endotracheal cuff and descend along the folds of the cuff wall to the lower respiratory tract and subsequently cause VAP." ¹⁸ "VAP occurs in a considerable proportion of patients undergoing mechanical ventilation and is associated with substantial morbidity, a two-fold mortality rate, and excess cost. Given these findings, strategies that effectively prevent VAP are urgently needed." ³⁸

"The causes of VAP are usually bacteria. The primary route of pathogen entry into the trachea is through the tube or by passage of bacteria around the cuff of the endotracheal tube." ⁴⁰

VAP is predominantly caused by microaspiration

- Q Aspiration of gastric contents is common in critically ill patients and is a risk factor for VAP ^{23 36}
- Prevention of microaspiration of contaminated oropharyngeal and gastric secretions is helpful to prevent VAP ³⁶
- Q Tracheal tubes which allow subglottic secretion drainage reduce the incidence of VAP ³⁵
- Endotracheal and tracheostomy tubes that can drain subglottic secretions via dedicated additional ports are increasingly recognised as one of the effective components of strategies to reduce VAP²²
- Additional risk factors include sedation, mechanical ventilation, a PVC cuff on a tracheal tube, under inflation of the tracheal cuff³⁶
- A deficient cuff seal allows contaminated secretions into the lungs ^{13 44}

Subglottic Secretion Drainage is not enough to prevent aspiration past the cuff

"The use of an endotracheal tube with polyurethane cuff and Subglottic Secretion Drainage helps prevent early- and late-onset VAP." ¹⁹

Venner PneuX[™] System adds the benefit of a silicone cuff to this VAP prevention recommendation

"Subglottic Secretion Drainage (SSD's) role will need to be re-evaluated in function of the potential industrial advances – ET cuff material, finer regulation of the cuff pressure, ET's providing several orifices allowing SSD."¹⁷

Venner PneuX[™] System low-volume, low-pressure silicone cuff with automated maintenance of cuff pressure and multiport subglottic drainage is engineered for safety and prevents aspiration past the cuff ²¹

Maintaining tracheal cuff pressure can reduce aspiration risk ²³

Manually inflated ETT or TT cuffs do not maintain a seal

"There is a need to redesign the process for maintaining cuff pressure within the target range."¹

- Patients have physiological and anatomical differences
- Q Manually inflated ETT or TT cuffs are not capable of continuously fitting each patient
- Q Manually inflated cuffs do not keep up with the movement of and to a patient
- Q Folds in the PVC cuff material compromise the seal in the trachea ¹³
- Q Variations in cuff pressure are common in intubated patients ³⁰
- High-volume, low-pressure cuffs consistently leak²¹

Venner PneuX[™] System Engineered to protect

Leakage of ETTs after 1 hour of placing in the "model trachea"

Each cuff was inflated to the correct pressure according to the manufacturer's instructions using a hand-held manometer. If continuous cuff pressure monitors were recommended, these were used to maintain cuff inflation during experiments.

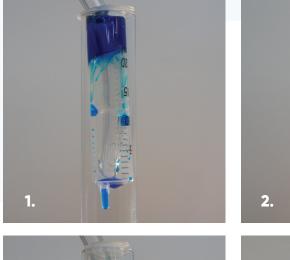
- 1. Mallinckrodt[™] TaperGuard[™] Evac Oral Endotracheal Tube
- 2. KimVent[™] MICROCUFF[™] Subglottic Suctioning Endotracheal Tube
- **3.** Mallinckrodt[™] Hi-Lo Oral Endotracheal Tube, Lanz System
- **4.** Mallinckrodt[™] SealGuard[™] Evac Endotracheal Tube
- 5. Portex Soft Seal® Cuff Tracheal Tube
- 6. Portex SACETT[™] Suction Above ET Cuff
- 7. Teleflex ISIS[®] HVT[™]

8. Venner PneuX[™] ETT

Photographs taken as part of the Mariyaselvam et al study ²¹

Venner PneuXTM (Image No. 8) low-volume, low-pressure cuff with automated maintenance of cuff pressure, prevented aspiration past the cuff.²¹

"The low volume low pressure cuffed tracheal and tracheostomy tubes reduce pulmonary aspiration in the benchtop models and in anaesthetized and critically ill patients." ⁴⁶











3.





Venner PneuX[™] ETT

Designed to be used in conjunction with the Venner PneuX TSM[™] Cuff Pressure Controller

90% of artificial airway devices are ETTs in mechanically ventilated intensive care unit (ICU) admissions in the UK.²²

The silicone cuff material of the Venner PneuX[™] ETT is designed to prevent folds in the cuff wall material to help eliminate aspiration that occurs with PVC/PUC cuffs

 Low Volume, Low Pressure silicone cuff ensures a low and consistent intracuff pressure is transmitted to the tracheal wall

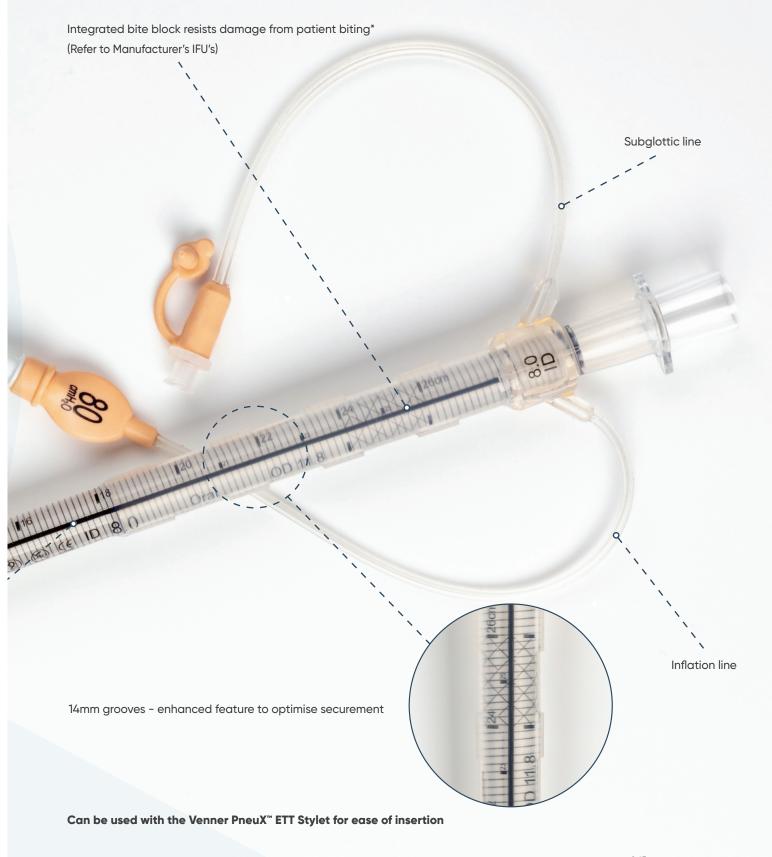
Venner PneuX[™] System allows the general recommendation that tracheal wall seal pressure be persistently maintained at 20–30 cm H₂O ^{18 34}

3 Subglottic Channels/Ports for routine subglottic secretion drainage, irrigation and avoids suction failure from a single port ⁷

Wire reinforced (nitinol) silicone airway tube, prevents kinking and occlusion and is designed to be flexible to follow anatomical contours and minimize pressure injuries compared with more rigid tubes

Wenner Medical (\$ingapore)

Boat tip, with bevel design and murphy eye aids the passage of Venner PneuX[™] ETT through the larynx into the trachea reducing the risk of airway damage or occlusion



Humidification with a heated humidifier is strongly advised to help reduce luminal occlusion with any ETT ^{8 43}

"There is a tendency for reduced colonization in the Venner PneuX™ ETT with longer intubation times. This may have an impact on reducing the incidence of late-onset VAP." ³⁹

Venner PneuX[™] TT

Designed to be used in conjunction with the Venner PneuX TSM[™] Cuff Pressure Controller

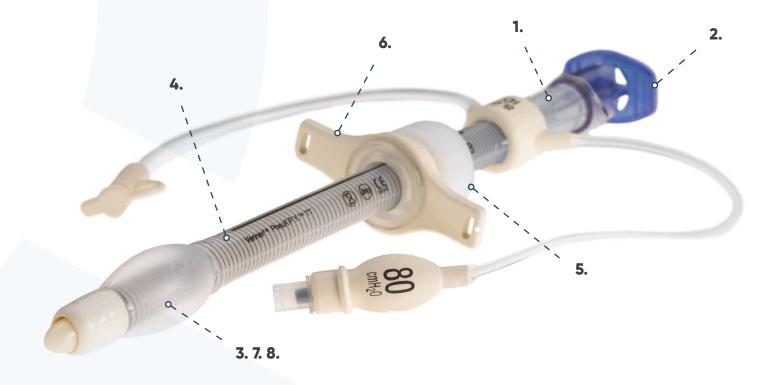
Tracheostomies are used as artificial airway devices in 10% of all mechanically ventilated intensive care unit (ICU) admissions in the UK.¹⁴

Early, compared with late or no, tracheostomy might be associated with a lower incidence of pneumonia; a finding that could question the present practice of delaying tracheostomy beyond the first week after translaryngeal intubation in mechanically ventilated patients. ⁴¹ "An inflated tracheostomy tube cuff cannot prevent aspiration; it only slows the already aspirated bolus movement in the lungs. When water runs into the subglottic space above the inflated cuff, it almost completely disappears down the longitudinal channels caused by folds in the cuff wall material." ⁴⁵

"Sub-glottic suction tracheostomy tubes should be used as standard for new tracheostomy. These tubes can reduce the incidence of pneumonia (as part of a bundle of care) and can allow Above Cuff Vocalisation (ACV) without needing to change the tube." ¹⁵

"Humidification is important for patients with tracheostomies and laryngectomies, especially if the cuff is inflated and therefore the natural warmth and humidification of the nose bypassed." ¹⁵

- Venner PneuX[™] TT does not require an inner cannula, so the internal diameter of 7, 8 or 9mm is not reduced. This minimises the impact on work of breathing⁶
- 2. Obturator fits in the airway tube to guide placement. The tip is designed to aid the passage through the surgical opening of a tracheostomy stoma. The obturator also has a hole for a guidewire to pass through
- **3.** The silicone cuff material of the Venner PneuX[™] TT is designed to prevent folds in the cuff wall material to help eliminate aspiration that occurs with PVC/PUC cuffs
- **4.** 3 Subglottic Channels/Ports for routine Subglottic Secretion Drainage, irrigation and avoids suction failure from a single port ⁷
- 5. Neck plate with adjustable flange/lock nut
- 6. Winged tube-holder
- 7. Venner PneuX[™] System allows the general recommendation that tracheal wall seal pressure be persistently maintained at 20–30 cm H2O ^{18 34}
- 8. The silicone cuff material of the Venner PneuX[™] TT is designed to prevent folds in the cuff wall material to help eliminate aspiration that occurs with PVC/PUC cuffs



Can be used in conjunction with the Venner PneuX[™] PDT Introducer Set

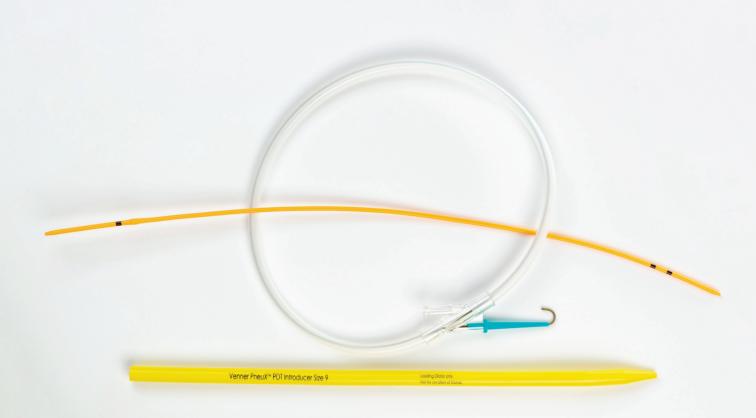
Humidification with a heated humidifier is strongly advised to help reduce luminal occlusion with any ETT⁸⁴³

Venner PneuX[™] PDT Introducer Set

Designed exclusively for use with the Venner PneuX[™] TT

An innovative advancement intended for controlled, elective, subcricoid insertion of the Venner PneuX[™] TT, in combination with compatible PDT Sets.

The Venner PneuX[™] TT is longer than a conventional tracheostomy tube and so the longer Venner PneuX[™] PDT Introducer and Wire Stiffener is required for convenient placement.



Above Cuff Vocalisation (ACV)

ACV is particularly useful for patients who cannot tolerate or be managed with a deflated tracheostomy tube cuff.²⁴ With the cuff inflated the most effective protection from microaspiration can be maintained – **Venner PneuX™ TT** achieves this.

Cuff Pressure Monitoring

"It is suggested to use appropriate measurement tools (continuous cuff pressure regulator) instead of manual intermittent controlling of the endotracheal tube cuff pressure. If this was to be instigated into practice then the complications caused by increasing or decreasing the cuff pressure are thus minimized." ²⁵ "Continuous control of P(cuff) is associated with significantly decreased microaspiration of gastric contents in critically ill patients". ^{31 32}

"Another preventive strategy for avoiding the progression of subglottic secretions into the lower respiratory tract is to maintain optimal cuff pressure." ¹⁸ "Connecting and disconnecting manometer reduced cuff pressure on average by 4.78 cm H₂O after 1 minute and 5.89 cm H₂O after 5 minutes." ³ "It is desirable during anaesthesia to use a continuous in-built intracuff pressure measurement technique." ¹⁶

"Some systems can continually monitor and adjust cuff pressure within set parameters and these systems likely control cuff pressures more accurately and more safely than intermittent manual checks." ¹⁵ – Venner PneuX[™] System achieves this Equipment should include... a system or device to measure or monitor cuff pressure. (Intensive Care Society, 2020)

Venner PneuX TSM[™] Cuff Pressure Controller

Designed exclusively for use with the Venner PneuX[™] ETT/TT and Venner PneuX[™] Extension Set

The unique technology of automated maintenance of cuff pressure control is supported by first class leading benefits:

- Prevents microaspiration past the cuff
- Q Maintains the seal during patient/equipment movement
- Automates tracheal tube cuff pressure control



A clinical seal may be achieved at an intracuff pressure of between 80-90 cm H₂O. This corresponds to the default tracheal wall seal pressure setting on the Venner PneuX TSM[™] Cuff Pressure Controller of 20 mmHg (approx. 30 cmH₂O) and does not need to be adjusted unless necessary following clinical review.

Venner PneuX TSM[™] Cuff Pressure Controller is designed for the monitoring, maintenance and regulation of pressure within the cuffs of the Venner PneuX[™] ETT/TT, saving time for the ICU Nurse and compensating for interactions that move the tube within the patient and create risk.

Coronavirus COVID-19 Pandemic

≥98%

of COVID-19 patients had qualifying CPIS \geq 6 on Day 2 ⁴

100%

of patients that spent ≥9 days on ICU acquired a bacterial co-infection 11

40.8%

of patients developed VAP ⁹

Consensus guidelines for managing the airway in patients with COVID-19 recommend to "monitor airway cuff pressure carefully to avoid airway leak." ⁵ - Venner PneuX^{TT} System achieves this

A VAP diagnosis is challenging in COVID patients as the clinical presentation is shared ¹⁰. A device that prevents VAP saves time spent diagnosing a condition introduced by the failure of an ETT or TT cuff in preventing aspiration past the cuff **- Venner PneuX[™] System achieves this**

"Where available, automatic tracheostomy cuff pressure monitoring devices will minimise these risks." ³⁷ - Venner PneuX[™] System achieves this

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Venner PneuX™ System

Ordering information

| Code: | Description: | ID (mm) | OD (mm) | Unit of Issue |
|----------|---|---------|---------|------------------|
| 7160PETM | Venner PneuX [™] ETT Size 6.0* MR Conditional | 6.0 | 9.9 | 10 |
| 7170PETM | Venner PneuX™ ETT Size 7.0 MR Conditional | 7.0 | 10.9 | 10 |
| 7180PETM | Venner PneuX™ ETT Size 8.0 MR Conditional | 8.0 | 11.8 | 10 |
| 7190PETM | Venner PneuX™ ETT Size 9.0 MR Conditional | 9.0 | 12.8 | 10 |
| 7170PTTM | Venner PneuX™ TT Size 7.0 MR Conditional | 7.0 | 10.9 | 10 |
| 7180PTTM | Venner PneuX™ TT Size 8.0 MR Conditional | 8.0 | 11.8 | 10 |
| 7190PTTM | Venner PneuX™ TT Size 9.0 MR Conditional | 9.0 | 12.8 | 10 |
| 7170PDTS | Venner PneuX™ PDT Introducer Set for use with Venner PneuX™ TT Size 7.0 | n/a | n/a | 10 |
| 7180PDTS | Venner PneuX™ PDT Introducer Set for use with Venner PneuX™ TT Size 8.0 | n/a | n/a | 10 |
| 7190PDTS | Venner PneuX™ PDT Introducer Set for use with Venner PneuX™ TT Size 9.0 | n/a | n/a | 10 |
| 7000PTSM | Venner PneuX TSM™ Cuff Pressure Controller | n/a | n/a | |
| 7000PEXT | Venner PneuX [™] Extension Set | n/a | n/a | 10 |
| 7000PSTY | Venner PneuX™ Stylet for use with Venner PneuX™ ETT (All sizes) | n/a | n/a | 10 |

*Size 6.0 not avaliable in the UK.

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