PneuX P.Y.™ Endotracheal Tube

Designed exclusively for use with the

Venner™ PneuX P.Y.™ System

CONTENTS

1. DEVICE DESCRIPTION

Venner™ PneuX P.Y.™ ENDOTRACHEAL TUBE

Venner™ PneuX P.Y.™ Endotracheal Tube (ETT) is an ETT designed to be used for patients undergoing tracheal intubation during extended periods (not more than 30 days) and for evacuation or drainage of secretion from the subglottic space. It is also compatible with tracheal intubation during routine anaesthesia. It is supplied sterile, in MRI-compatible and Non-MRI compatible forms, for single use only.

Venner™ PneuX P.Y.™ ETT is a flexible cuffed tube with a Murphy Eye and a standard 15mm connector. Venner PneuX P.Y.™ ETT is a medical-grade, wire-reinforced, silicone tube which incorporates 3 auxiliary channels for subglottic irrigation and drainage. The airway tube cuff is of low volume design and when used as described below, generates low mucosal wall pressure. The device incorporates a tapered sleeve (integrated bite-block) to resist damage from biting. It is recommended that the Venner™ PneuX P.Y.™ ETT be used in conjunction with the Venner™ Tracheal Seal Monitor (TSM) or a standard pressure gauge inflator.

2. FEATURES

Boat Tip with Murphy Eye – The tip of Venner™ PneuX P.Y.™ ETT is beveled in two directions to aid passage of the tube through the larynx and into the trachea.

Cuff – Venner™ PneuX P.Y.™ ETT cuff is low volume-low pressure silicone design which helps in generating low mucosal wall pressure. It shall be inflated to a constant pressure of 80cm H_2O. The patient should already be intubated with a Venner™ PneuX P.Y.™ ETT inflated by conventional means when attached to the TSM to maintain inflation at the desired pressure. The elastic characteristics of the Venner™ PneuX P.Y.™ cuff are calibrated such that only a constant portion of the intracuff pressure is transmitted to the tracheal wall. An intracuff pressure of 80cm H_2O provides a calculated tracheal wall pressure of approx. 20 mmHg (approx. 30cm H_2O) depending upon the diameter and shape of the patients' trachea and the ventilation pressures.

Wire Reinforced Silicone Airway Tube – Depth markings are printed on the airway tube. These indicate the distance to the distal tip of the tube. The tube also has a printed black line to aid orientation of the tube. The tube features a nitinol (MRI-compatible) or a stainless steel (Non-MRI compatible) reinforcing wire to prevent kinking or occlusion of the tube. The internal diameter of the tube varies according to the size of the Venner™ PneuX P.Y™ ETT.

Subglottic Line, Subglottic Connector, Reservoir – There are three suction channels running alongside the airway lumen.

The three suction channels are subglottic and above the cuff, to enable drainage of accumulated secretions. The proximal ends of these suction channels join into a reservoir which acts as a common space for all three lumens to meet and the outlet is linked to the subglottic line and subglottic connector. The subglottic connector is used for drainage of secretions or for irrigation by using a syringe. The subglottic connector has a female luer that only attaches to a luer slip or luer lock syringe.

Connector – The 15mm standard connector is clear and is moulded per the ISO standard for Anaesthetic and respiratory equipment – Conical connectors (Part 1: Cones and sockets) (ISO 5356-1). The connector is used for attachment to a ventilator or anaesthesia equipment so that air or anaesthetic gases can be provided to the patient from external gas supplies.

Inflation Line – This is a small diameter silicone tube that connects to the cuff. It is used to inflate and deflate the cuff.

Pilot Balloon – The pilot balloon is joined to the inflation line and when in use, the balloon will provide the anaesthetist with a rough indication of the pressure within the cuff.

Pilot (Check) Valve – A check pilot valve that is inserted to the inflation tube. The valve is usually in the closed position, preventing the flow of air. When a luer tipped syringe is engaged into the valve, the valve opens and air can flow into or out of the cuff, thus inflating or deflating it accordingly. When the cuff is inflated and the syringe removed, the valve will prevent leakage of air and thus maintains the pressure in the cuff to enable a proper seal at the trachea wall.

Detent Tab – The Detent Tab (or Vent Tab) is inserted into the check valve to engage the check valve in an "open" position. This is to equilibrate the pressure in the cuff to the atmospheric pressure. When removing from packaging this tab is in place and must be removed prior to use.

Reservoir with tapered sleeve and integrated bite-block - Reinforced to resist damage from biting. If excessive or forceful biting is encountered consider using a bite block. There are 10 indents either side of the tube to facilitate correctly securing the tube. Tubes should be secured in place to prevent slippage as per clinical judgement and hospital policy.

3. WARNINGS AND CAUTIONS

Venner™ PneuX P.Y.™ ETT is a single use device and should not be reused. Reuse may cause cross infection and reduce product reliability and functionality.

Venner™ PneuX P.Y.™ ETT should be inflated to 80cmH_2O or the lowest pressure to achieve clinical seal to ensure that cuff pressure and tracheal wall pressure are correctly controlled (Pressure Controlled Inflation). Venner™ PneuX P.Y.™ ETT cuff SHOULD NOT be inflated with an excessive fixed volume of air (unless inflated to achieve a clinical seal), which, in common with other cuffs, may lead to an abnormally high intra-cuff pressure and consequently abnormally high tracheal wall pressures.

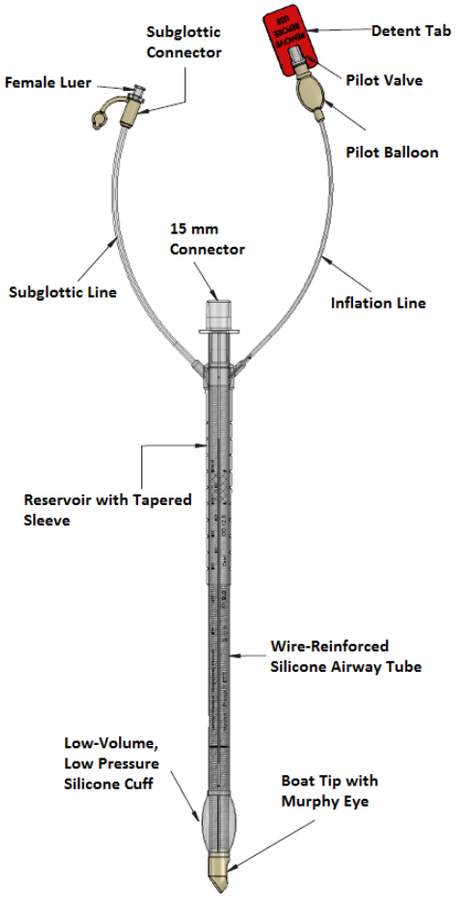

Figure 1: Venner™ PneuX P.Y™ ETT

This may result in tracheal damage and/or cuff herniation. When using Venner™ Tracheal Seal Monitor normally the default settings of 20mmHg (approx. 30cmH_2O) tracheal wall pressure should be used. This equates to an intra-cuff pressure of approximately 80cmH_2O.

Inadequate anaesthesia or muscle relaxant may cause the glottis to close, preventing entry of Venner™ PneuX P.Y.™ ETT in to the larynx.

If a stylet is used during intubation, ensure it does not protrude from the distal tip and Murphy Eye.

Diffusion of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure. It is recommended that the device be used with the Venner™ Tracheal Seal Monitor or a standard pressure gauge inflator in order to minimise these changes.

Do not use force under any circumstances.

Do not use if the package has been previously opened or damaged.

CAUTION: The Venner™ PneuX P.Y.™ ETT is available in MRI-compatible and Non-MRI compatible forms. Only MRI-compatible tubes may be used in an MRI environment.

4. PRECAUTIONS

The cuff, pilot balloon and valve should be tested (by inflation and complete deflation) prior to use, as indicated in section 7 (Preparation for Use). Do not use Venner™ PneuX P.Y.™ ETT if the cuff is damaged, the pilot balloon is showing any signs of deterioration or abnormality, or if the inflation valve mechanism is displaying any signs of deficiency.

It is assumed that the patient is anaesthetised and paralysed and has been appropriately pre-oxygenated prior to commencing intubation.

Clinical judgment should be used in the selection of the appropriate ETT size for each patient. Recommendation:
Adult males normally require a Venner™ PneuX P.Y.™ ETT size 9.0 ID

Adult females normally require a Venner™ PneuX P.Y.™ ETT size 8.0 ID

Intubation and extubation should be performed using currently accepted medical practices. Subglottic drainage of secretions and oral suction should be performed prior to cuff deflation and extubation.

WARNING: Venner™ PneuX P.Y.™ ETT is not intended to be, and should never be cut.

Take care to avoid damaging the cuff during intubation. If the cuff is or becomes damaged, extubate the patient and discard the tube.

Always ensure the 15mm connector is securely seated in the breathing circuit to prevent disconnection during use.

Non-standard dimensions of some connectors on ventilator or anaesthesia equipment may lead to difficulty in attaching the tracheal tube 15mm connector. Use only with equipment having standard 15mm connectors. Pressure gauge inflator or other devices should not be left inserted in the inflation pilot valve for extended periods of time. The resulting stress could crack the pilot valve, causing the cuff to deflate.

If the pilot valve has failed, then reconnecting the tube will result in re-inflation of the cuff and the Venner™ Tracheal Seal Monitor should simply remain connected at all times until extubation is deemed necessary.

Ensure that all Venner™ PneuX P.Y.™ ETTs are inspected to ensure that the clinicians are satisfied that they can support the tube in their normal practice.

5. ADVERSE REACTIONS

Reported adverse reactions associated with ETTs are many and diverse. Consult standard textbooks and medical literature for specific adverse reaction information. The subglottic space should normally be maintained empty to prevent aspiration due to unintentional cuff deflation, endobronchial intubation, stomal displacement of the cuff, excessive coughing causing dilation of the trachea or the presence of abnormal tracheal anatomy (e.g. triangular or sabre trachea). As with all tracheal tubes, luminal occlusion can occur due to a time dependent build-up of secretions in the distal tube or the sudden passage of a large mucus plug or blood clot, this complication can be minimised by ensuring adequate humidification. Active humidification is strongly advised. As for all mechanically ventilated patients there should always be immediate access to a clinician expert in airway management for urgent tube exchanges. There is some data that the combination of a relatively non-stick coating of the tube lumen and active humidification together is associated with reduced build-up of secretions in the tube.

6. PREPARATIONS FOR USE

Venner™ PneuX P.Y.™ ETT is delivered sterile and for single use only.

CAUTION: Careful handling is essential. Venner™ PneuX P.Y.™ ETT is made of medical-grade silicone which can be torn or perforated. Avoid contact with sharp or pointed objects at all times. Do not grasp the cuff with forceps. Avoid cuff contact with teeth. Sharp spurs of cartilage may rarely perforate cuffs.

CAUTION: Venner™ PneuX P.Y.™ ETT must be handled with caution to avoid cross contamination and damage to the tube or cuff. Surgical gloves should be worn at all times during testing, preparation and insertion.

6.1 PRE-PERFORMANCE TESTING

Inflate Venner™ PneuX P.Y.™ ETT cuff with 50ml of air using a syringe for 30 seconds to test both the cuff and the integrity of the valve.

- Ensure the cuff does not stick to the tube on first inflation. If sticking occurs, gentle sterile digital manipulation resolves this. Any tendency of the cuff to deflate indicates the presence of a leak and if suspected this can be checked by submerging the whole tube assembly under water and observing bubbles. Visually check that the boat tip, cuff, airway tube, inflation line, inflation balloon, drain tube, subglottic connector and 15mm connector are not damaged, kinked or occluded.

- If there is a leak or the cuff does not inflate appropriately, the device is damaged. Do not use.

- Proceed to deflate the cuff fully.

- Check the patency of the subglottic ports at this stage by instilling sterile saline down the subglottic connection port.

- Ensure the 15mm connector is attached to the Venner™ PneuX P.Y.™ ETT.

- The device is now ready for use.

Proceed to re-inflate the cuff with a desired amount of air for the procedure prior to connecting with the Venner™ Tracheal Seal Monitor.

7. AIRWAY MANAGEMENT

7.1 INTUBATION AND TUBE EXCHANGE

Intubation, tube exchange and extubation should be performed following currently accepted medical techniques. Expert clinical judgment should be used in choosing the suitable tube size for each patient. Recommendation:

Adult males normally require a Venner™ PneuX P.Y.™ ETT size 9.0 ID

Adult females normally require a Venner™ PneuX P.Y.™ ETT size 8.0 ID

7.2 CUFF INFLATION

Once the patient is intubated, the cuff should be inflated to a clinical seal. This will normally correspond to an intra-cuff pressure of 80cmH_2O. Inflation may be performed with a standard pressure gauge inflator and then attaching the Venner™ Tracheal Seal Monitor. If clinical seal is not achieved at 80cmH_2O the cuff pressure should be increased incrementally until seal is achieved. If >90cmH_2O is required for clinical seal then the tube should be checked for correct position, correct size, blockage of the inflation port, excessive airway pressures and tracheal anatomical abnormalities. Normally the lowest cuff pressure to achieve clinical seal is appropriate although intermittent reductions in cuff pressure to test the seal are not recommended unless the subglottic space has been emptied and sufficient Trendelenburg position and PEEP are applied to reduce leakage past the cuff.

WARNING: Venner™ PneuX P.Y.™ ETT should always be initially inflated to 80cmH_2O as printed on the pilot balloon to ensure that cuff pressure and tracheal wall pressure are correctly controlled. Inflating Venner™ PneuX P.Y.™ ETT cuff with a fixed volume of air may lead to an abnormally high intra-cuff pressure and consequently abnormally high tracheal wall pressure. This may result in tracheal damage and/or cuff herniation.

7.3 TUBE POSITION AND SECURING

Once the cuff has been inflated, connect Venner™ PneuX P.Y.™ ETT to the airway circuit and check for correct placement by confirming breath sounds and monitoring end-tidal CO_2. Routine post-intubation clinical evaluation to exclude endobronchial intubation or high/ laryngeal placement of the cuff should be performed.

Ventilator circuits should be supported adequately and tension on the tube avoided. Forceful pulls on the tube will risk extubation.

Secure Venner™ PneuX P.Y.™ ETT in place. Correct fixation and care to protect the tube and ventilation circuit from excessive or persistent pulling forces is essential to prevent unplanned extubation.

Venner™ PneuX P.Y.™ ETT is flexible and is designed to follow the contours of the patient's airway so as to minimise pressure injury that is associated with more rigid tubes. The path of Venner™ PneuX P.Y.™ ETT in the upper airway may therefore be longer than that of a rigid PVC tube, thus requiring a longer length of tube from lips to trachea. If a PVC tube is replaced with Venner™ PneuX P.Y.™ ETT, then fixation at the lips of Venner™ PneuX P.Y.™ ETT may be 1-2cm greater than the preceding PVC tube.

If an accidental extubation occurs, then Venner™ PneuX P.Y.™ ETT should be disconnected from Venner™ Tracheal Seal Monitor, aspirate the oropharynx if indicated, the cuff should be deflated, and if reintubation is required then a new Venner™ PneuX P.Y.™ ETT should be used.

Clinically accepted practice should be used for maintaining Venner™ PneuX P.Y.™ ETT in the patient's airway. A chest radiograph is normally required to confirm correct positioning.

7. 4 MAINTAINING CUFF PRESSURE

It is important that the correct intra-cuff pressure is maintained at all times. The correct pressure is 80cmH_2O and should not normally be allowed to fall below 60-70cmH_2O or rise above 90cmH_2O except in exceptional circumstances dictated by clinical judgement. Patients requiring high levels of positive end expiratory pressure and high peak inflation pressure, patients undergoing sustained recruitment manoeuvres, patients in whom the tracheal tube is too small for the trachea in which it is placed or patients with unusual tracheal shapes (ie triangular tracheal cross-section) may require tracheal wall pressures greater than 30cmH_2O (approx. 20mmHg) and therefore an intra-cuff pressure greater than 80cmH_2O. In this circumstance the clinician can simply adjust the intra-cuff pressure to achieve seal at the lowest possible intra-cuff pressure.

Venner™ Tracheal Seal Monitor

Venner™ Tracheal Seal Monitor should normally be used to maintain the device at the correct pressure.

Intermittent Pressure Measurement and Correction

If Venner™ TSM is not being used for example, during patient transfer of greater than 1 hour, then the cuff pressure should be measured and corrected at least once every 1 hour.

CAUTION: Care should be taken to ensure the subglottic drainage of secretions and oral suction are performed prior to cuff pressure measurement in case of accidental cuff deflation.

If an air leak appears during use, the possibility of accidental extubation of the cuff into the glottis should be considered. This is possible if Venner™ PneuX P.Y.™ ETT is unintentionally withdrawn. If this occurs when Venner™ PneuX P.Y.™ ETT is connected to Venner™ Tracheal Seal Monitor, then the cuff may inflate to achieve seal and maintain ventilation. It is essential, however, that this possibility is considered and can be confirmed by direct laryngoscopy. Reintubation can be performed by deflation of the cuff and reinsertion of the tube by a clinician skilled in advanced airway care. When using Venner™ Tracheal Seal Monitor the alarm may sound and the malposition light may illuminate (for further information see Venner™ Tracheal Seal Monitor Instructions for Use).

7.5 SUBGLOTTIC SECRETION DRAINAGE

The subglottic connector may be used to aspirate secretions. The following guidance suggests how the subglottic connector may be used. However, this may need to be modified in light of specific clinical observation.

Subglottic secretion drainage should be intermittent and not continuous. Continuous or semi-continuous techniques with subglottic drainage tubes can cause suction injury to the trachea. Intermittent drainage with the Venner™ PneuX P.Y.™ System is safe so long as the cuff seal is maintained so that secretions are held safely between drainage episodes.

Perform subglottic aspirations as required (in accordance with local guidelines for example when clinically indicated or once every shift change) or whenever cuff pressure measurements, corrections or cuff deflations are planned. Attach a sterile 10ml luer syringe to the subglottic connector and briefly apply vacuum by pulling the plunger to the 10mL mark and maintain the vacuum until the flow of secretions have ceased (normally 10-20 seconds). Dispose all aspirated material in a controlled manner (in accordance with the hospital's protocol) or send for microbiological culture.

WARNING: If a culture is sent, clearly label as subglottic/ oropharyngeal NOT tracheal secretions. secretions to avoid confusion when laboratory reports become available.

When appropriate, extubate the patient using currently accepted medical techniques and discard Venner™ PneuX P.Y.™ ETT in accordance with the hospital protocol.

7.6 ORAL AND PERIORAL CARE

The peri- and intra-oral portion of Venner™ PneuX P.Y.™ ETT should be checked carefully on a 4 to 6 hourly basis to ensure that excessive pressures are not exerted on the oral cavity, tongue or lips. This oral and peri-oral care may involve moving the proximal tube to varying parts of the oral cavity. Oral care and irrigation can be much more liberal than with conventional high volume, low pressure (HVLP) cuffed tubes because the lungs are protected from pulmonary aspiration.

7.7 SUBGLOTTIC IRRIGATION

Increasingly Venner™ PneuX P.Y™ System has been used in combination with subglottic irrigation (with 50-200mL sterile or n/saline). This provides excellent oral, laryngopharyngeal and subglottic cleansing and has been associated with the prevention of ventilator-associated pneumonia [1]. Clinicians however must consider the risks of unintentional saline pulmonary aspiration if the cuff is deflated unintentionally or if excessive pressures are used to instill the saline (thereby exceeding the tracheal seal/ wall pressure) and balance this against the benefits. For awake and lightly sedated patients, warmed fluid or initial instillation of a few mL of 1-2% lidocaine can be considered immediately prior to irrigation to improve comfort, reduce cough and help avoid bradycardia. Excessive coughing can cause saline to pass the cuff requiring clinical judgement and skill to determine the temperature of the saline, the rapidity of irrigation flow, the sensitivity of the patient's airway and the sedation level. Irrigation may best be performed at times when sedation or analgesia has been increased associated with other procedures.

8. SYMBOLS USED ON LABELLING

CE 0086	Complies to the European Medical Device Directive 93/42/EEC
EC REP	The name and address of the European Authorised Representative as required by the European Medical Device Directive 93/42/EEC
	Read instructions before use
	Do not reuse
STERILE EO	Sterilised by ethylene oxide
	Latex-Free
	Use by
LOT	Lot number
REF	Product code
	Keep away from sunlight
	XXXX Year of manufacture
	**MR conditional** **MRI Safety Information** Non-clinical testing has demonstrated Venner™ PneuX P.Y™ ETT MRI, (max. 372 x 12.8 mm) is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions: • Static magnetic field of 1.5 and 3 Tesla**,** with • Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode) Under the scan conditions defined above, Venner™ PneuX P.Y™ ETT MRI, (max. 372 x 12.8 mm) is expected to produce a maximum temperature rise of less than: 1.2°C **(2 W/kg, 1.5 Tesla) RF-related temperature increase** 0.9°C **(2 W/kg, 3 Tesla) RF-related temperature increase** after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 5.2 mm from Venner™ PneuX P.Y™ ETT MRI when imaged only with a gradient echo pulse sequence and a 3 Tesla MR system.

9. MANUFACTURER'S WARRANTY

Venner Medical (Singapore) Pte Limited warrants Venner™ products against faulty materials or manufacturing defects. Single use products are warranted against faulty materials or manufacturing defects at time of delivery to customer. Warranty is applicable only if purchased from an authorised distributor.

VENNER MEDICAL (SINGAPORE) PTE LIMITED DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

10. MANUFACTURER'S INFORMATION

The information given in this document is correct at the time of going to press. The manufacturer reserves the right to improve or modify the products without prior notification.

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At the end of its useful life the device should be disposed of using the medical institution's recycling/disposal procedures in an environmentally conscious manner that respects local or national regulation.

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