PneuX P.Y.™ Tracheostomy Tube

Designed exclusively for use with the

Venner™ PneuX P.Y.™ System

CONTENTS

1. DEVICE DESCRIPTION

Venner™ PneuX P.Y.™ TRACHEOSTOMY TUBE

The Venner™ PneuX P.Y.™ Tracheostomy Tube (TT) is an TT is an endotracheal tube designed to be used for patients undergoing tracheal intubation during extended periods (<24 hours but not more than 30 days). It is also compatible with tracheal intubation during routine anaesthesia. It is supplied sterile, in MRI-compatible (MR Conditional) and non-MRI compatible forms, for single use only.

The Venner™ PneuX P.Y.™ TT Tube is a flexible cuffed tube with an adjustable flange and a standard 15mm connector. The airway tube is a medical-grade, wire-reinforced silicone 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 an adjustable flange for improved patient comfort and security and comes with a flexible obturator. It is recommended that the Venner™ PneuX P.Y.™ TT Tube be used in conjunction with the Venner™ Tracheal Seal Monitor (TSM) or a standard pressure gauge inflator.

2. FEATURES

The Venner™ PneuX P.Y.™ TT Tube consists of the following main components:

- Tip – The tip of the Venner™ PneuX P.Y.™ TT Tube is to aid passage of the tube through the surgical opening of tracheostomy stoma.
- Cuff – The Cuff of the Venner™ PneuX P.Y.™ TT Tube is of low volume low pressure design which helps in generating low mucosal wall pressure. It shall be inflated to a constant pressure of 80cm H_2O. This may be performed manually with a standard pressure gauge inflator or the Venner™ Tracheal Seal Monitor.
- Wire Reinforced 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 and flange. The tube is made from medical grade silicone and features a stainless steel or nitinol 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.™ TT Tube.
- Fixation Block – To fix the position of the tracheostomy tube in the patient and to prevent unnecessary movement during use.
- Adjustable Flange – To provide an opening on each end for neck strap to go through and secure the device in place once inserted into patient.
- Lock Nut – To adjust the correct positioning of Fixation Block by loosening or tightening the lock nut.
- Suction / Drain Tube, Subglottic Connector, Reservoir – There are three suction lumens running alongside with the airway lumen. The port cutting of the suction lumens is just above the proximal end of the cuff for ease of suction. The proximal end of the suction lumens joins into a reservoir which acts as a common space for all three lumens to meet and the outlet is linked to the suction tube and subglottic connector. The subglottic connector is used for suctioning of secretions or for irrigation by using a 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 5356-1:2004). 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 tube and when in use, the balloon will provide the anaesthetist with a rough indication of the pressure within the cuff.
- Check Valve – A one-way check valve that is inserted to the inflation balloon. The valve is usually in the closed position, preventing the flow of air. When a luer tipped syringe is engaged into the valve, the seal is lifted 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 maintaining the pressure in the cuff to enable a proper seal.
- Detent Tab – The Detent 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.
- Obturator – The obturator has a hole allowing the passage of a guidwire which can be used at the clinicians discretion. It should be noted that feedback from clinicians proficient in performing a percutaneous tracheostomy with the Venner™ PneuX P.Y.™ TT and a third party kit has suggested that a tight stoma should be avoided as sufficient space for the less rigid silicone tube may be required to facilitate passage.

3. WARNINGS AND CAUTIONS

The Venner™ PneuX P.Y.™ TT Tube is a single use device and it shall not be reused. Reuse may cause cross infection and reduce product reliability and functionality.

- If lubricant is used during insertion, ensure it does not occlude the tube lumen.
- Diffusion of nitrous oxide, oxygen, or air may increase or decrease cuff volume and pressure. It is recommended that the device be used with a standard pressure gauge inflator or with the Venner™ Tracheal Seal Monitor in order to minimise these changes.

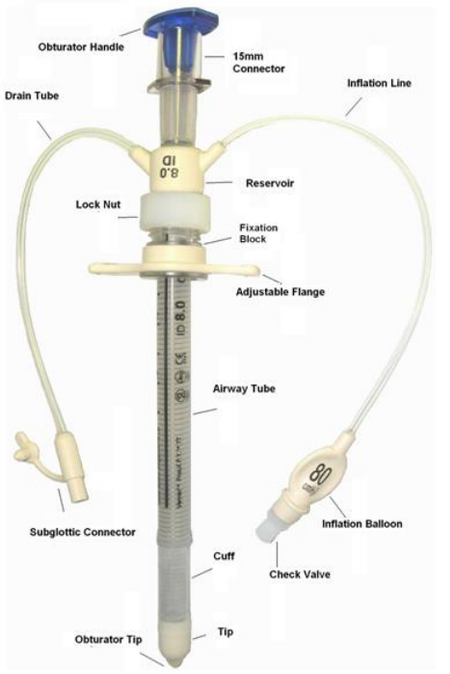

Figure 1: Venner™ PneuX P.Y™ Tracheostomy tube

- The Venner™ PneuX P.Y.™ TT Tube should always be inflated to 80cmH2O to ensure that cuff pressure and tracheal wall pressure are correctly controlled (Pressure Controlled Inflation). The Venner™ PneuX P.Y.™ TT Tube cuff SHOULD NOT be inflated with a fixed volume of air, which, in common with other cuffs, may lead to an abnormally high intra-cuff pressure and consequently abnormally high tracheal wall pressures. This may result in tracheal damage and/or cuff herniation. When using the Venner™ Tracheal Seal Monitor, normally the default setting of 20mmHg (approx. 30cmH2O) tracheal wall pressure should be used. This equates to an intra-cuff pressure of approximately 80cmH20.
- Do not use force under any circumstances.

4. PRECAUTIONS

- Do not use if the unit pouch has been previously opened or damaged.
- 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 the Venner™ PneuX P.Y.™ TT Tube if the cuff is damaged, if 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 Venner™ PneuX P.Y.™ TT Tube size for an each patient. Recommendation: Venner™ PneuX P.Y.™ TT Tube size 8 for females and size 9 for males.
- Intubation and extubation should be performed using currently accepted medical practices. The subglottic space should be emptied prior to cuff deflation and extubation.

- Only use water-soluble lubricants with the Venner™ Pneux P.Y.™ TT Tube. Follow the lubricant manufacturer's application instructions. Excessive amounts of lubricant on the inner surface of the tube could result in either a lubricant plug or a clear film that may partially, or totally, block the lumen and the airway or which may cause a risk of aspiration.

- The Venner™ Pneux P.Y.™ TT Tube 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 dimensioning 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.

- Three-way stopcocks or other devices should not be left inserted in the inflation valve for extended periods of time. The resulting stress could crack the valve, causing the cuff to deflate.

- Prolonged connection to the Venner™ Tracheal Seal Monitor may result, on very rare occasions, in valve failure, causing the cuff to deflate on disconnection of the connecting tubing. It is desirable therefore to empty the subglottic space prior to planned disconnection of the Venner™ PneuX P.Y.™ TT Tube from the Venner™ Tracheal Seal Monitor tubing. If the valve has failed, then reconnection of the tubing will result in reinflation of the cuff and the Venner™ Tracheal Seal Monitor should simply remain connected at all times until extubation is deemed necessary.

- The connection between the Venner™ PneuX P.Y.™ TT Tube and the breathing circuit should be checked at regular intervals.

- Ensure that all Venner™ PneuX P.Y.™ TT Tube 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 tracheostomy tubes 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.

6. PREPARATIONS FOR USE

The Venner™ PneuX P.Y.™ TT Tube is delivered sterile and for single use only.

Caution: Careful handling is essential. The Venner™ PneuX P.Y.™ TT Tube 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.

Caution: The Venner™ PneuX P.Y.™ TT Tube must be handled with extreme caution to avoid cross contamination and damage to the tube or cuff. Sterile gloves should be worn at all times during testing, preparation and insertion.

6.1 PRE-PERFORMANCE TESTING

Inflate Venner™ PneuX P.Y.™ TT 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, adjustable flange, 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.™ TT.

- 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: Venner™ PneuX P.Y.™ TT Tube size 8 for females and size 9 for males.

A sufficient sized stoma is required to be made by the operator (greater than the external diameter of the tracheostomy tube) to allow easy free passage of the Venner™ PneuX P.Y.™ TT Tube into the trachea.

7.2 CUFF INFLATION

Once the tube has been inserted, the cuff should be inflated to a "just seal pressure". This will normally correspond to an intra-cuff pressure of 80cmH2O. 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 80cmH2O the cuff pressure should be increased incrementally until seal is achieved. If >90cmH2O 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.

Warning: The Venner™ PneuX P.Y.™ TT Tube should always be inflated to 80cmH2O to ensure that cuff pressure and tracheal wall pressure are correctly controlled. Inflating the Venner™ PneuX P.Y.™ TT Tube 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 the Venner™ PneuX P.Y.™ TT Tube to the airway circuit and check for correct placement by confirming breath sounds and monitoring end-tidal CO2. Routine post-intubation clinical evaluation to exclude endobronchial intubation should be performed.

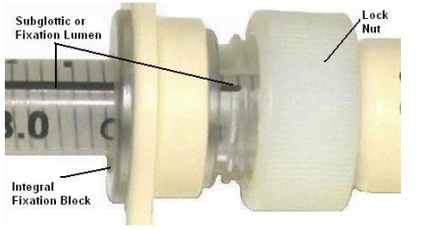

Figure 2: Venner™ PneuX P.Y.™ Tracheostomy Tube and Fixation-Block Alignment

Loosen the lock nut on the integral fixation-block and move it so that it fits snugly at the patient's neck. Tighten the lock nut sufficiently to grip the tube for practice requirements. Ventilator circuits should be supported adequately and tension on the tube avoided. The flange needs to be stitched or secured snugly with the skin. Open or inadequately tightened lock nuts and/or forceful pulls on the tube will risk extubation.

Warning: Avoid unduly over-tightening the lock nut to prevent occlusion of the subglottic and/or cuff inflation channels by aligning the black line in one of the four grooves on the integral fixation-block. If occlusion occurs then simply loosen the nut a little until the channel is open again.

Secure the Venner™ PneuX P.Y.™ TT Tube in place by attaching the retaining neck strap to the adjustable flange and secure around the patient's neck. Dual fixation is possible with a second tape (around the tube) to minimise further the chance of accidental decannulation. Correct fixation and care to protect the tube and ventilation circuit from excessive or persistent pulling forces is essential to prevent unplanned decannulation. If an unplanned or accidental removal occurs, then the Venner™ PneuX P.Y.™ TT Tube should be disconnected from the Venner™ Tracheal Seal Monitor, the cuff should be deflated and if reintubation is required then a new Venner™ PneuX P.Y.™ TT Tube should be used.

Clinically accepted practice should be used for maintaining the Venner™ PneuX P.Y.™ TT Tube in the patient's airway. A chest radiograph is normally required to confirm correct positioning. The adjustable flange allows any correction of the position of the tube to occur.

7. 4 MAINTAINING CUFF PRESSURE

It is important that the correct intra-cuff pressure be maintained at all times. The correct pressure is 80cmH2O and should not normally be allowed to fall below 60-70cmH2O or rise above 90cmH2O. Patients requiring high levels of positive end expiratory pressure and high peak inflation pressure, and patients undergoing sustained recruitment maneuvers, patients in whom the tracheal tube is too small for the trachea in which it is placed or patients with unusual tracheal shapes (i.e. triangular tracheal cross-section) may require tracheal wall pressures greater than 30cmH2O (approx. 20mmHg) and therefore an intra-cuff pressure greater than 80cmH2O. In this circumstance the clinician can simply titrate the intra-cuff pressure to achieve seal at the lowest possible intra-cuff pressure.

1.Venner™ Tracheal Seal Monitor (TSM)
The Venner™ Tracheal Seal Monitor should normally be used to maintain the device at the correct pressure.
2.Intermittent Pressure Measurement and Correction
If the Venner™ Tracheal Seal Monitor is not being used, then the cuff pressure should be measured and corrected, at least every 1 hour. (Caution: Care should be taken to ensure the subglottic space is empty prior to cuff pressure measurement in case of accidental cuff deflation.)

If an air leak appears during use, the possibility of partial withdrawal of the cuff into the tracheostomy stoma should be considered. This is possible if the Venner™ PneuX P.Y.™ TT Tube is unintentionally withdrawn. If this occurs when the Venner™ PneuX P.Y.™ TT Tube is connected to the Venner™ Tracheal Seal Monitor, then the cuff may inflate to achieve seal and maintain ventilation. It is essential, however, that this possibility is considered. After emptying the subglottic space, reintubation can be performed by deflation of the cuff and reinsertion of the tube by a clinician skilled in advanced airway care.

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 drainage

Subglottic secretion drainage should be intermittent and not continuous. Continuous or semi-continuous techniques can cause suction injury to the trachea. Perform subglottic irrigation and aspiration as required (for example every 2-4 hours) 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 until the flow of secretions has 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. If a culture is sent clearly label as subglottic/ oropharyngeal NOT tracheal secretions.

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

7.6 SUBGLOTTIC IRRIGATION

Increasingly the PneuX System has been used in combination with subglottic irrigation (with 50-200mL 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 instils 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 installation of a few mL of 1-2% lidocaine can be considered immediately prior to irrigation to improve comfort, reduce cough and help avoid bradycardia – again the risks and benefits require assessment of the individual patient and the clinical situation.

References[1] Doyle et al. The incidence of VAP using PneuX System with or without elective endotracheal tube exchange. BMC Res Notes. 2011 Mar 30;4:92

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	Latex-Free
	Use by
LOT	Lot number
REF	Product code
	Keep away from sunlight
	XXXX Year of manufacture
MR	**MR conditional** **MRI Safety Information** Non-clinical testing has demonstrated Venner™ PneuX P.Y™ TT 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™ TT 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™ TT 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 the 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.

Manufactured by
Venner Medical (Singapore) Pte Ltd
35 Joo Koon Circle
Singapore 629110

EU Authorised Representative
Advena Ltd
Pure Offices, Plato Close, Warwick CV34 6WE UK

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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