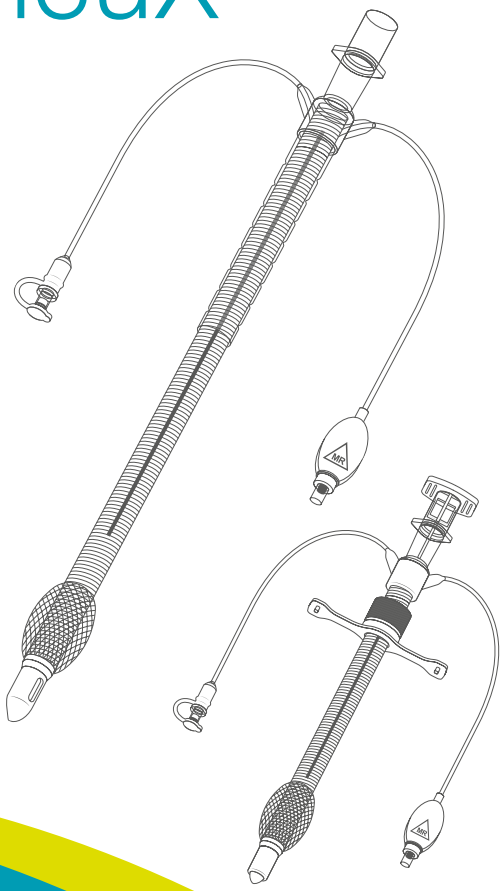
PNEUX
Life Systems

Venner PneuX™ ETT/TT

EN (UK) INSTRUCTIONS FOR USE



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Contents

1. Device Description

Venner PneuX™ ETT/TT

The Venner PneuX™ Endotracheal Tube (ETT) / Tracheostomy Tube (TT) is designed to be used in patients requiring tracheal intubation during routine anesthesia, over extended periods (not more than 30 days) or for the evacuation of drainage and secretion from the subglottic space. It should be used in medical institutions such as hospitals and extended care facilities by trained medical professionals. The device is MRI-compatible and supplied sterile for single use only.

The Venner PneuX™ ETT/TT is a flexible cuffed tube with a standard 15 mm connector. The Venner PneuX™ ETT has a Murphy Eye. The Venner PneuX™ ETT/TT is a medical-grade, wire-reinforced, silicone tube, which incorporates 3 auxiliary channels for subglottic irrigation and drainage. The airway tube cuff is a low-volume, low-pressure cuff. The device incorporates a tapered sleeve (integrated bite block) to resist damage from biting. It is recommended that the Venner PneuX™ ETT/TT is used in conjunction with Venner PneuX TSM™. The Venner PneuX™ TT has an adjustable flange.

2. Features

Cuff: The Venner PneuX™ ETT/TT cuff is a low volume-low pressure silicone cuff that is designed to exert low pressure on the mucosal wall. The cuff should be inflated to a constant pressure of 80 cmH_2O. Once a patient has been intubated with a Venner PneuX™ ETT/TT and it has been inflated by conventional means, it can be attached to Venner PneuX TSM™ to maintain a constant cuff pressure. The elastic characteristics of the Venner PneuX™ cuff are calibrated such that a consistent intracuff pressure is transmitted to the tracheal wall. An intracuff pressure of 80 cmH_2O provides a calculated tracheal wall pressure of approx. 30 cmH_2O (approx. 20 mmHg) depending on the diameter and shape of the patient's 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 and features a nitinol (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™ ETT/TT.

Subglottic Line, Subglottic Connector, Reservoir: There are three channels running alongside the airway lumen. The three channels are subglottic and above the cuff, to enable drainage of accumulated secretions or to enable irrigation. The proximal ends of these channels join into a reservoir which acts as a common space for all three lumens and the outlet is linked to the subglottic line and subglottic connector.

The subglottic connector is used for the drainage of secretions or for syringe irrigation. The subglottic connector has a female luer that only attaches to a luer slip or luer lock syringe.

Connector: The 15 mm 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 can be attached 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.

Inflation Balloon: The inflation 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 of 80 cmH_2O. The balloon is printed with a MR symbol to identify the tube is an MRI-Compatible tube.

Check Valve: A check valve that is attached to the inflation tube. The valve is usually in the closed position, preventing the flow of air.

Figure 1: Venner PneuX™ ETT

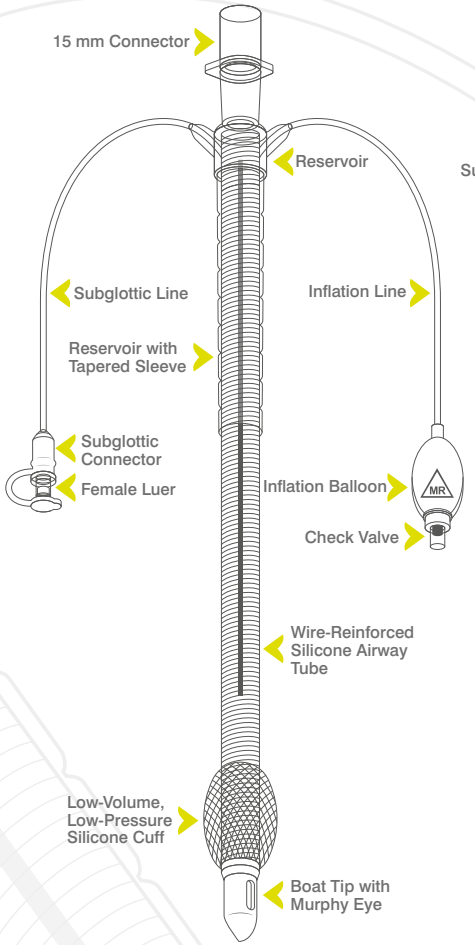
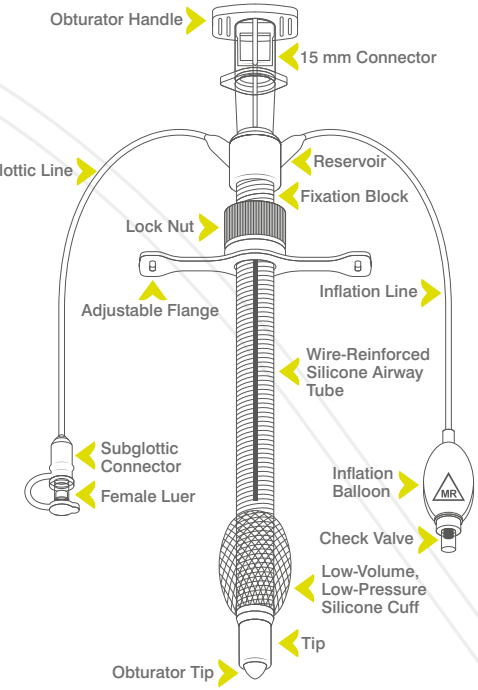


Figure 2: Venner PneuX™ TT



When a luer-tipped syringe is engaged with 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 is removed, the valve will prevent leakage of air and maintain the pressure in the cuff to establish an effective seal with 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 the device from its packaging the tab must be removed prior to use.

Specific features of the Venner PneuX™ ETT

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

Reservoir with tapered sleeve and integrated bite block (ETT): Reinforced to resist damage from biting. If excessive or forceful biting is encountered, consider using an additional standard bite block. There are indents either side of the tube to enable the tube to be secured in place. Tubes should be secured in place to prevent slippage (Section 6: Tube position and securing).

Specific features of Venner PneuX™ TT

Tip (TT): The tip of the Venner PneuX™ TT is designed to aid the passage of the tube through the surgical opening of a tracheostomy stoma.

Adjustable Flange (TT): The flange has an opening on each end for the neck strap to pass through to secure the device in place.

Fixation Block (TT): The fixation block is designed to fix the position of the tracheostomy tube and to prevent unnecessary movement during use.

Lock Nut (TT): Loosening or tightening the lock nut enables the correct positioning of the fixation block.

Obturator (TT): The obturator has a hole allowing the passage of a guidewire 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™ 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. Precautions

The cuff, inflation balloon and check valve should be tested (full inflation and complete deflation) prior to use (Section 5: Pre-performance testing). Do not use the Venner PneuX™ ETT/TT if: the cuff is damaged, the inflation balloon is showing any signs of deterioration or abnormality, or if the check 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 intubation.

Clinical judgement should be used in the selection of the appropriate size for each patient.

Recommendation:The Venner PneuX™ ETT/TT size 8.0 ID for females and size 9.0 ID for males

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.

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

Non-standard dimensions of some connectors on ventilators or anaesthesia equipment may lead to difficulty in attaching the tracheal tube 15 mm connector. Use only with equipment that utilizes standard 15 mm connectors.

Ensure that all Venner PneuX™ ETT/TTs are inspected prior to use.

Prolonged connection to Venner PneuX TSM™ may result, on very rare occasions, in valve failure, causing the cuff to deflate on disconnection of the connecting tubing. Subglottic secretion drainage should be performed prior to planned disconnection of the Venner PneuX™ ETT/TT from Venner PneuX TSM™ tubing. If the valve has failed, then reconnection of the tubing will result in reinflation of the cuff and the Venner PneuX TSM™ should remain connected at all times until extubation is deemed necessary.

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

4. Adverse Reactions

Reported adverse reactions associated with ETT/TTs 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 build-up of secretions in the distal tube over time 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.** There are some data that the combination of a relatively non-stick coating of the tube lumen and active humidification is associated with reduced build-up of secretions in the tube.

As for all mechanically ventilated patients, there should always be immediate access to a clinician skilled in advanced airway care for urgent tube exchanges.

5. Pre-performance Testing

Deflate the cuff completely. Inflate the cuff with 20 ml of air 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, this may be resolved with gentle sterile digital manipulation. 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. Should there be a leak or the cuff fails to inflate appropriately, the device is damaged. Do not use. Visually check that the tip, cuff, airway tube, inflation line, inflation balloon, drain tube, subglottic connector,15 mm connector, adjustable flange (TT), obturator (TT) and obturator handle (TT) are not damaged, kinked or occluded. Do not over inflate the cuff.

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

Ensure the 15 mm connector is attached to the Venner PneuX™ ETT/TT.

6. Airway Management

Intubation and tube exchange

Intubation, tube exchange and extubation should be performed following currently accepted medical techniques. Expert clinical judgement should be used in choosing a suitable tube size for each patient (Section 3: Precautions).

For TT intubation, an appropriately sized stoma should be made by the operator (greater than the external diameter of the tracheostomy tube) to allow easy free passage of the Venner PneuX™ TT into the trachea.

Cuff inflation

Once the tube has been inserted, the cuff should be inflated to a “just seal pressure”. This will normally correspond to an intracuff pressure of 80-90 cmH_2O. Inflation may be performed with a standard handheld pressure inflator/manometer before attaching Venner PneuX TSM™. If a clinical seal is not achieved at 80-90 cmH_2O, the cuff pressure should be increased incrementally until a seal is achieved. If >90 cmH_2O is required to achieve a 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 a clinical seal is appropriate. 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 (Positive End-Expiratory Pressure) are applied to reduce the risk of leakage past the cuff.

Tube position and securing

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

The Venner PneuX™ ETT/TT is flexible and is designed to follow the contours of the patient's airway to minimise the risk of pressure injuries associated with more rigid tubes. The path of the Venner PneuX™ 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 the Venner PneuX™ ETT, then fixation at the lips of the Venner PneuX™ ETT may be 1-2 cm greater than the preceding PVC tube.

The Venner PneuX™ ETT should be secured in place using standard techniques as per your hospital protocols. This may be with tape ties or third party fixation devices. Lateral grooves may help prevent slippage of some designs of tube ties and devices. A flexible tube such as the Venner PneuX™ ETT/TT offers advantages of lessening potential trauma to the lower airway however it requires attention to appropriate continuous fixation at the lips to prevent unintentional extubation.

Secure the Venner PneuX™ TT 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 further minimize the chance of accidental decannulation.

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

Disconnection

Should an accidental extubation (ETT) or decannulation (TT) occur, then the Venner PneuX™ ETT/TT should be disconnected from Venner PneuX TSM™. Prior to disconnection, perform subglottic secretion drainage to ensure the subglottic space is clear of secretions. Disconnect the Venner PneuX™ Extension Tube the check valve of the Venner PneuX™ ETT/TT before disconnecting it from the air outlet on Venner PneuX TSM™. If reintubation is required, then a new Venner PneuX™ ETT/TT should be used.

Maintaining cuff pressure

It is important that the correct intracuff pressure is maintained at all times. The correct pressure is 80-90 cmH_2O and should not normally be allowed to fall below 60 cmH_2O or rise above 90 cmH_2O. This equates to approximately 30 cmH_2O (approx. 20 mmHg) tracheal wall pressure. 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 (i.e., triangular tracheal cross-section) may require tracheal wall pressures greater than 30 cmH_2O (approx. 20 mmHg) and therefore an intracuff pressure greater than 80-90 cmH_2O. In this circumstance, the clinician can simply adjust the intracuff pressure to achieve a seal at the lowest possible intracuff pressure.

Venner PneuX TSM™

Venner PneuX TSM™ should be used to maintain the Venner PneuX™ ETT/TT at the correct pressure (for further information see: Venner PneuX TSM™ IFU).

Intermittent pressure measurement and correction

During patient transfer when Venner PneuX TSM™ is not being used, the cuff pressure control should be maintained temporarily (at hourly intervals) with a standard handheld cuff pressure inflator/manometer until the Venner PneuX™ ETT/TT is reconnected to the Venner PneuX TSM™.

Should an air leak appear during use, in the case of the Venner PneuX™ ETT, the possibility of accidental extubation of the cuff into the glottis should be considered. In the case of the Venner PneuX™ TT, the possibility of partial withdrawal of the cuff into the tracheostomy stoma should be considered. This is possible if the Venner PneuX™ ETT/TT is unintentionally withdrawn. If this occurs when the Venner PneuX™ ETT/TT is connected to the Venner PneuX TSM™, then the cuff may inflate to achieve a seal and maintain ventilation. 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.

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. Perform subglottic secretion drainage as required (for example every 2-4 hours) or whenever cuff pressure measurements, corrections or cuff deflations are planned. Attach a sterile 10 ml luer syringe to the subglottic connector and briefly apply a vacuum by pulling the plunger to the 10 ml mark and maintain the vacuum until the flow of secretions has ceased (normally 10-20 seconds). Dispose of all aspirated material in a controlled manner (in accordance with hospital protocol) or send for microbiological culture.
If a culture is sent, clearly label it as subglottic/ oropharyngeal NOT tracheal secretions. When appropriate, extubate the patient, (Section 6: Disconnection) and discard the Venner PneuX™ ETT/TT in accordance with hospital protocol.

Subglottic irrigation

Increasingly, the Venner PneuX™ System has been used in combination with subglottic irrigation (with 50-200 ml saline, which should be performed every 12 hours or shift change). This provides excellent oral, laryngopharyngeal and subglottic cleansing, and has been associated with the prevention of ventilator-associated pneumonia [1]. Clinicians wishing to introduce fluid into the subglottic space at
a pressure that might exceed 30 cmH_2O (approx. 20 mmHg) may choose to increase the calculated tracheal wall pressure temporarily during the irrigation up to a maximum of 50 mmHg. For awake and lightly sedated patients, warmed fluid or the initial instillation of a few ml of 1-2% lidocaine can be considered immediately prior to irrigation to improve comfort, reduce cough and help to 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 be best performed at times when sedation or analgesia are increased to undertake other procedures.

Oral and perioral care for ETTs

The perioral and intraoral portion of the Venner PneuX™ ETT should be checked carefully on a 4-6 – hourly basis to ensure that excessive pressures are not exerted on the oral cavity, tongue or lips. This oral and perioral 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.

7. Warnings and Cautions

Do not use if the Venner PneuX™ ETT/TT pouch has been previously opened or damaged.

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

The Venner PneuX™ ETT/TT should be inflated to 80-90 cmH_2O or to the lowest pressure to achieve a clinical seal. This ensures that cuff pressure and tracheal wall pressure are correctly controlled.

The Venner PneuX™ ETT/TT cuff SHOULD NOT be inflated with an excessive fixed volume of air as this may, in common with other cuffs, lead to an abnormally high intracuff pressure and, consequently, abnormally high tracheal wall pressure. This may result in tracheal damage and/or cuff herniation. The Venner PneuX TSM™ should always be set at the minimum setting to achieve clinical air-leak seal. This will normally be the default setting of 30 cmH_2O (approx. 20 mmHg) tracheal wall pressure or above but rarely less. This equates to an intracuff pressure of 80-90 cmH_2O. Depending on patient anatomy and ventilator settings higher or lower settings may achieve air seal and should be used.

Do not overinflate the cuff, as this can result in rupture and subsequent deflation, or cuff distortion, which may lead to airway blockage and/or patient injury.

Excessive biting or chewing the Venner PneuX™ ETT may result in luminal occlusion or perforation of the tube. Consider using an additional standard bite block.

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

If a stylet is used during intubation, this should not protrude beyond the Murphy Eye (ETT).

The connection between the Venner PneuX™ ETT/TT and the breathing circuit should be checked at regular intervals.

Careful handling is essential. The Venner PneuX™ ETT/TT 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.

Do not use force under any circumstance.

The Venner PneuX™ ETT/TT is not intended to be, and should never be, cut.

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

A handheld cuff pressure inflator/manometer or other devices should not be left inserted in the check valve for extended periods of time. The resulting stress could crack the check valve, causing the cuff to deflate.

The Venner PneuX™ ETT/TT 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.

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

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

Only use water-soluble lubricants with the Venner PneuX™ ETT/TT. Follow the lubricant manufacturer's application instructions. Should lubricant be used during insertion, ensure it does not occlude the tube lumen.

8. Manufacturer's Warranty

PneuX Life Systems warrants Venner™ products against faulty materials or manufacturing defects. Single-use products are warranted against faulty materials or manufacturing defects at the time of delivery to the customer. The 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.

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

10. Symbols Used on Labelling

	Consult Instructions for Use (IFU)
CE 0086	Complies with 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
	Year of manufacture
	Manufacturer
	Keep away from sunlight
LOT	Lot number
REF	Product code
	Single use
	Read instructions before use
Rx only	Federal law restricts this device to sale by or on the order of physician
	Not made with natural rubber latex
	Contains Phthalates
STERILE EO	Sterilised by ethylene oxide
	Use by
	Do not use if package is damaged
MR	MR conditional MRI Safety Information

Non-clinical testing has demonstrated that the Venner PneuX™ ETT/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
- A 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™ ETT/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™ ETT/TT MRI when imaged only with a gradient echo pulse sequence and a 3 Tesla MR system.

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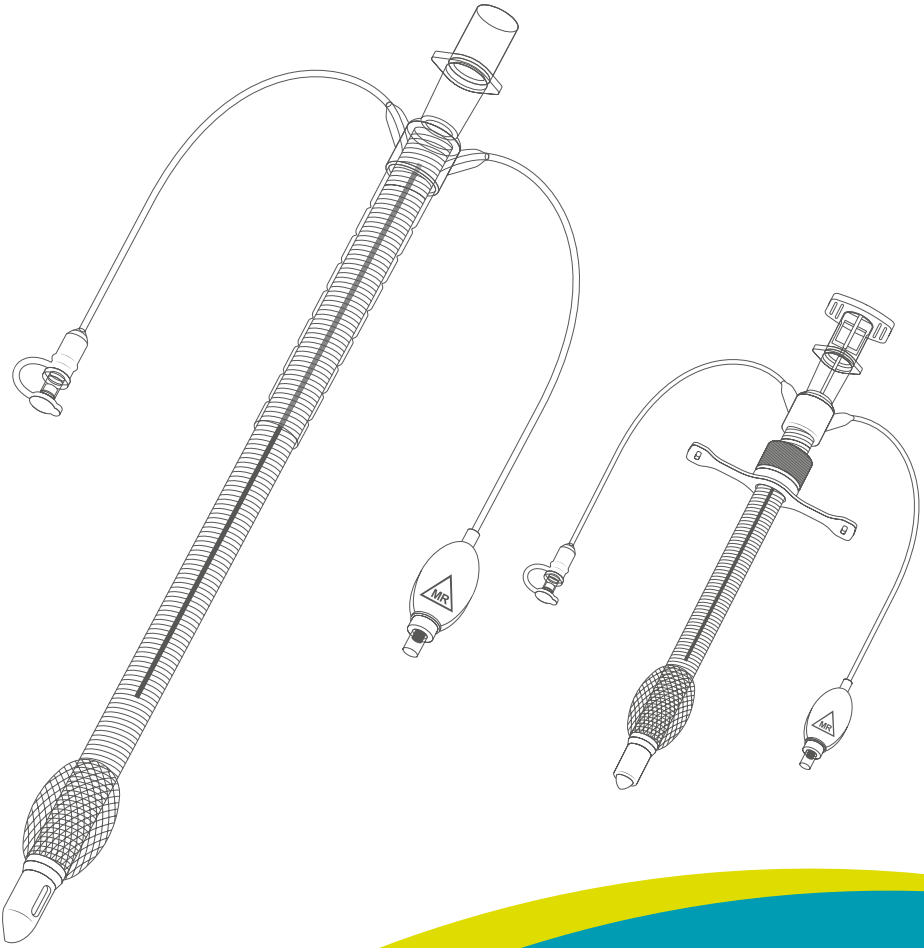

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