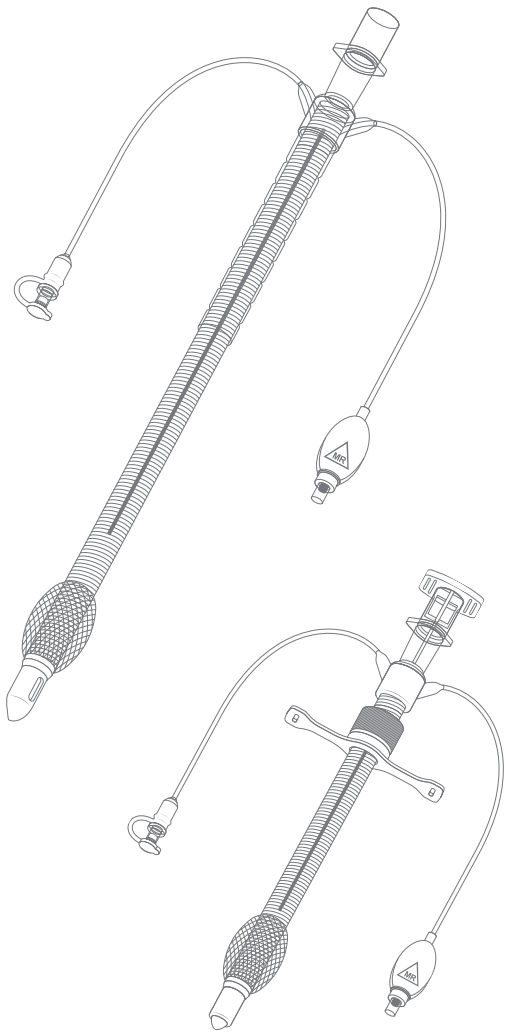
Venner PneuX™ System

en	INSTRUCTIONS FOR USE
de	BEDIENUNGSANLEITUNG
es	INSTRUCCIONES DE USO
fr	MODE D'EMPLOI
it	ISTRUZIONI PER L'USO
pt	INSTRUÇÕES DE UTILIZAÇÃO



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These instructions for use are for the following Venner PneuX™ products:

Product code	Description	Quantity/box
901160	Venner PneuX™ ETT size 6.0 mm	10
901170	Venner PneuX™ ETT size 7.0 mm	10
901180	Venner PneuX™ ETT size 8.0 mm	10
901190	Venner PneuX™ ETT size 9.0 mm	10
902170	Venner PneuX™ TT size 7.0 mm	10
902180	Venner PneuX™ TT size 8.0 mm	10
902190	Venner PneuX™ TT size 9.0 mm	10

Only Venner PneuX™ ETT and TT are to be used with the Venner PneuX TSM™ Cuff Pressure Controller and Venner PneuX™ Extension Tube.

en

Contents

1. Device description

1.1 Indications for use

Venner PneuX™ ETT

The Venner PneuX™ Endotracheal Tube (ETT) (Figure 1), single use device, is intended for patients undergoing tracheal intubation during routine anaesthesia or over extended periods (not more than 30 days) and for the evacuation or drainage of secretions from the subglottic space.

Venner PneuX™ TT

The Venner PneuX™ Tracheostomy Tube (TT) (Figure 2), single use device, is intended for patients undergoing tracheal intubation during extended periods (not more than 30 days) of intensive or critical care to facilitate ventilation and for the evacuation or drainage of secretions from the subglottic space. May also be used for safe and effective Above Cuff Vocalisation (ACV). NB. Flow rates will be lower than for larger subglottic ported TT's.

Both the Venner PneuX™ ETT/TT are single use, sterile and MRI-compatible (MR Conditional). They should be used in medical institutions such as hospitals and extended care facilities by trained medical professionals. The Venner PneuX™ ETT/TT is also recommended to be used with the Venner PneuX TSM™, a cuff pressure controller and the Venner PneuX™ Extension Tube as a complete system.

1.2 Common features

Low Volume, Low Pressure Silicone Cuff ensures that a low and consistent intracuff pressure is transmitted to the tracheal wall.

An intracuff pressure of 80 cmH_2O provides a calculated tracheal wall seal pressure of approx. 30 cmH_2O (~20 mmHg) depending on the patient's anatomy and ventilation pressures.

When a patient is intubated with a Venner PneuX™ ETT/TT and inflated by standard techniques, it can be attached to the Venner PneuX TSM™ via the Venner PneuX™ Extension Tube, to monitor, maintain and regulate cuff pressures.

Three Subglottic Channels/Ports, Reservoir, Subglottic Line, Subglottic Connector, Female Luer these subglottic channels/ports run from above the cuff to the airway tube before joining into a reservoir that acts as a common space for all channels/ports. From the reservoir an outlet links to the subglottic line and subglottic connector.

This design enables subglottic drainage of accumulated secretions and/or syringe irrigation via the subglottic connector, which has a female Luer for attachment to a Luer slip or Luer lock syringe.

Wire-Reinforced (Nitinol) Silicone Airway Tube prevents kinking or occlusion and is also designed to be flexible to follow anatomical contours and minimise pressure injuries compared with more rigid tubes. The depth markings indicate the distance to the distal tip of the tube and a printed black line aids orientation of the tube. The Nitinol wire is MRI compatible.

15 mm Connector for universal attachment to a ventilator or anaesthesia equipment.

Inflation Line connects the cuff for inflation and deflation.

Pilot Balloon connects the cuff to provide an indication of the pressure within the cuff.

Pilot Valve opens to allow free flow of air to the cuff for inflation or deflation when a Luer lock syringe is engaged. When the syringe is removed, the valve closes to prevent leakage of air and ensures the cuff is inflated.

- **Features specific to Venner PneuX™ ETT**

Boat Tip with Murphy Eye aids the passage of ETT through the larynx to the trachea with a bevel design and reduces the risk of airway occlusion.

Reservoir with tapered sleeve (integrated bite block) resists damage from biting. If excessive or forceful biting is encountered, consider using an additional standard bite block. There are indents on either side of the tube to prevent slippage and tube securement. (refer to: Tube positioning and securement).

- **Features specific to Venner PneuX™ TT**

Obturator fits in the airway tube of the TT and guides the TT placement. Its tip is designed to aid the passage through the surgical opening of a tracheostomy stoma. The obturator also has a hole which allows a guidewire to pass through, if clinically required.

Adjustable Flange has openings on each end for a neck strap to pass through.

Fixation Block fixes the position of the tube and prevents unnecessary movement during use. The lateral grooves on the insides of the fixation block resists slippage.

Lock Nut enables correct positioning of the fixation block through loosening or tightening it.

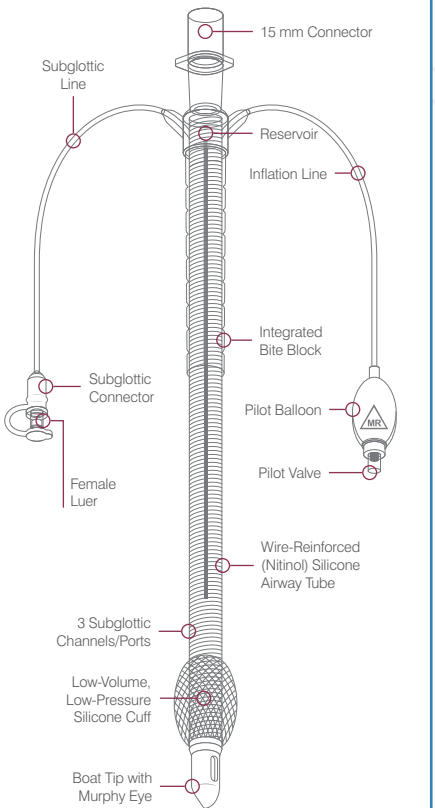

Figure 1: Venner PneuX™ ETT

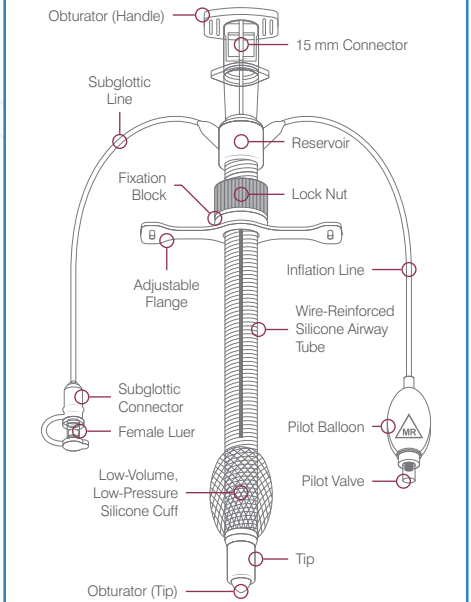

Figure 2: Venner PneuX™ TT

2. Operating instructions

2.1 Preparation for use

Sizing guide

The following serves as a sizing guideline for the Venner PneuX™ ETT/TT.

Venner PneuX™ ETT/TT size recommendation:

Females **size 8.0 mm (I.D.)**

Males **size 9.0 mm (I.D.)**

CAUTION: The flexible tube and cuff design of the Venner PneuX™ ETT/TT allows for larger tube I.D. than with equivalent PVC tubes.

It is important to exercise clinical judgement when selecting an appropriate size for each patient.

Inspection and pre-performance testing

Inspect all areas of the ETT/TT for any visible signs of damage once opened from the packaging pouch. Proceed to test the cuff and valve integrity as follows.

Deflate the cuff completely and re-inflate with 20 ml of air. Check if the:

- **Cuff sticks to the airway tube.** If sticking occurs, gentle manipulation may resolve this.
- **Cuff deflates gradually.** This suggests a leak and can be confirmed by immersing the tube in water and observing bubbles.
- **Subglottic channels/ports are patent.** Instil sterile saline through the subglottic connector and observe line patency.

If no abnormalities are found, proceed to deflate the cuff and prepare for intubation.

CAUTION: Do not use the ETT/TT if the packaging has been opened or damaged. Replace and repeat pre-performance or inform the local distributor.

2.2 Using the device

Intubation, tube exchange and extubation

Use currently accepted medical techniques when performing any of the above. When performing a Venner PneuX™ TT intubation, an appropriately sized stoma should be made to allow easy passage of the TT into the trachea.

CAUTION: Only use water-soluble lubricants with the Venner PneuX™ ETT/TT.

If a stylet is used to assist intubation, ensure that it does not protrude beyond the distal tip of the tube.

Prior to performing cuff deflation, or in the event of extubation (ETT) or decannulation (TT), whether intended or accidental, the ETT/TT should be disconnected from the Venner PneuX TSM™. Perform subglottic secretion drainage to clear the subglottic space prior to disconnection and maintain cuff pressure temporarily with a standard cuff manometer until a Venner PneuX™ ETT/TT is reconnected to the Venner PneuX TSM™. For details on disconnection, refer to the Venner PneuX TSM™ IFU.

Cuff inflation

Insert the ETT/TT and inflate to a clinical seal and check using a cuff manometer before connecting to the Venner PneuX TSM™. Do not overinflate the cuff. An intracuff pressure of 80 cmH_2O provides a calculated tracheal wall seal pressure of approx. 30 cmH_2O (~20 mmHg) depending on the patient's anatomy and ventilation pressures.

Normally the lowest cuff pressure to achieve a clinical seal is appropriate and should be increased incrementally if a clinical seal is not achieved between intracuff pressures of 80-90 cmH_2O. If it requires > 90 cmH_2O to achieve a clinical seal, be sure to check the tube for correct size and positioning (which should be mid to lower tracheal, not endobronchial or glottic), potential line blockage, excessive airway pressures or anatomical abnormalities.

CAUTION: Intermittently reducing cuff pressures to test the seal is not recommended unless the risks of leakage past the cuff are reduced (e.g. clearing the subglottic space, applying sufficient Positive End-Expiratory Pressure [PEEP] and Trendelenburg position).

Connect the ETT/TT to the ventilator circuit and confirm correct placement from 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.

Tube positioning and securement

Due to the flexible tube design of the Venner PneuX™ ETT/TT compared with other rigid PVC tubes, a longer length of tube from the lips to trachea is required following the path of the ETT in the upper airway. As such, take note that fixation at the lips may be 1-2 cm greater with the Venner PneuX™ ETT, if it will replace a PVC tube.

CAUTION: Ensure that the ETT/TT is positioned correctly at all times. The integrated bite block should remain between the patient's teeth and the airway tube. For the TT, ensure that the black line on the airway tube is aligned between the lateral grooves on the insides of the fixation block.

To secure the ETT, use securement devices such as tape ties or third party fixation devices with standard techniques as per your hospital protocols.

For the TT, consider dual fixation with a second tape (around the tube) if required, to reduce the risk of accidental decannulation.

Perform chest radiography to confirm correct positioning after ETT/TT securement.

CAUTION: Due to the flexibility of the tube, special attention should be given to maintain these appropriate fixation tapes/devices to prevent possible outward migration that could result in unintentional laryngeal placement or extubation. This may become evident if a trans-laryngeal air leak develops (or sounding of the leak or malposition alarms). Attempt tube re-insertion under direct vision or with a bronchoscope.

Continuous monitoring of fixation around the lips should be practised to prevent unintentional extubation.

Connection to Venner PneuX TSM™

The Venner PneuX TSM™ is an automated cuff pressure controller designed for the monitoring, maintenance and regulation of Venner PneuX™ ETT/TT cuff pressures. Attach the ETT/TT to the Venner PneuX TSM™ via the Venner PneuX™ Extension Tube. For instructions to connect, refer to the Venner PneuX TSM™ IFU.

CAUTION: Ensure all attachments are secure to prevent disconnection during use.

Cuff pressure maintenance

An appropriate intracuff pressure should be maintained at all times (refer to: Cuff inflation). A clinical seal may be achieved at an intracuff pressure of between 80-90 cmH_2O. This corresponds to the default tracheal wall seal pressure setting on the Venner PneuX TSM™ at 20 mmHg (approx. 30 cmH_2O) and should not be changed unless necessary following clinical review.

Following situations may require an increase in seal pressure above 20 mmHg (approx. 30 cmH_2O) either temporarily or to perform subglottic irrigation:

- Patients with high intrathoracic pressures who have a translaryngeal air leak with ventilation (particularly with high PEEP and peak pressure requirements).
  - If increased seal pressure is required to prevent a translaryngeal air leak, check the cuff position for unintentional carinal or laryngeal placement.
- Patients with abnormal tracheal anatomy.
- Patients intubated with an incorrect (smaller) ETT size.
- A volume recruitment manoeuvre which requires greater sustained intrathoracic pressure to prevent a translaryngeal air leak past the cuff.
- To introduce fluid into the subglottic space at a higher pressure in order to perform subglottic irrigation.

CAUTION: A clinical seal should always be achieved at the lowest possible intracuff pressure.

Disconnection

Before disconnecting the Venner PneuX™ ETT/TT, perform subglottic secretion drainage to clear the subglottic space (refer to: Subglottic secretion drainage).

If the ETT/TT is connected to the Venner PneuX TSM™, proceed to disconnect it from the Luer slip Connector of the Extension Tube and subsequently, disconnect the Luer lock Connector of the Extension Tube from the Venner PneuX TSM™, if required.

Cuff pressure should be maintained temporarily (at hourly intervals) with a cuff manometer until a new Venner PneuX™ ETT/TT is used for re-intubation and reconnection to the Venner PneuX TSM™ via the Venner PneuX™ Extension Tube (refer to: Connection to Venner PneuX TSM™).

CAUTION: The Venner PneuX™ ETT/TT will remain inflated for up to an hour without connecting to the Venner PneuX TSM™. During this time, cuff pressure should be monitored and maintained (where necessary) with a cuff manometer.

Positive End-Expiratory Pressure (PEEP) may provide additional protection during manual cuff pressure adjustments if it is indicated and deemed clinically safe.

Take care when using a cuff manometer or syringe for inflation due to the potential for variations in pressure.

Subglottic secretion drainage

The subglottic space should normally be maintained empty to reduce the risks of aspiration due to varying situations (e.g. unintended cuff deflation, endobronchial intubation, malpositioned tubes, etc).

The following guidance suggests how the subglottic connector may be used to aspirate secretions. Consider modifying based on specific clinical observations.

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 e.g. every 2-4 hours) or whenever cuff pressure measurements, corrections or cuff deflations are planned.

Attach a sterile 20 ml Luer syringe to the subglottic connector and briefly apply a vacuum by pulling the plunger to the 20 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.

CAUTION: If a culture is sent, clearly label it as subglottic/oropharyngeal NOT tracheal secretions.

Subglottic irrigation

Increasingly, the Venner PneuX™ System has been used in combination with subglottic irrigation (with 50-200 ml room temperature saline and performed every 12 hours or during shift change). This provides excellent oral, laryngopharyngeal and subglottic cleansing, and has been associated with the prevention of ventilator-associated pneumonia[1].

Irrigation may be best performed at times when sedation or analgesia are increased to undertake other procedures.

The following guidance suggests how subglottic irrigation may be done. Consider modifying based on specific clinical observations.

Instil the room temperature saline at a very slow rate so as not to exceed the pressure inside the cuff. The instillation should be performed by a clinician who has been trained in the procedure and a senior nurse should suction the saline from the mouth. It is important to note that there may be in excess of 20 ml of saline instilled before drainage from the mouth (or nose or stoma) occurs. Saline should continue to be instilled until the drainage is clear of debris.

CAUTION: If the patient shows sign of distress, the procedure should be abandoned.

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 seal 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.

Oral and perioral care for ETTs

The perioral and intraoral portion of the Venner PneuX™ 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 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.

CAUTION: Exercise care to move or reposition the ETT/TT with the cuff inflated. Clinical judgement should be used to avoid patient injury and cuff damage.

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.

2.3 During use

ETT/TT cuff sealing bench test

The performance information shown below was collected using a bench test that is intended to provide a comparison of the sealing characteristics of the Venner PneuX™ ETT/TT cuffs in a laboratory setting only. The bench test is not configured or intended to predict performance in the clinical setting.

Venner PneuX™ ETT cuff performance for size 6 mm [per ISO 5361 method]

Trachea diameter	Cuff Pressure hPa (cmH_2O)	Leakage rate range (mL/h)	
		50^{th} Percentile	90^{th} Percentile
Minimum 15 mm	27	0	8.48
Maximum 19 mm	27	0	8.48

Venner PneuX™ ETT/TT cuff performance for size 7, 8 and 9 mm [per ISO 5361 method]

Trachea diameter	Cuff Pressure hPa (cmH_2O)	Leakage rate range (mL/h)	
		50^{th} Percentile	90^{th} Percentile
Minimum 19 mm	27	0	8.48
Maximum 23 mm	27	0	8.48

Air leak

The occurrence of air leak may suggest that the:

- **ETT/TT has a loose connection.** Check both connections of the ETT/TT pilot valve with the Luer slip connector of the Extension Tube as well as the Luer lock connector of the Extension Tube with the Connector outlet on the Venner PneuX TSM™. Perform reconnection if required.
- **ETT/TT is malpositioned.** If an ETT is in place, the cuff may have moved into the larynx/pharynx resulting in a partial extubation. If a TT is in place, there could be a withdrawal into an open stoma or an accidental extubation. Proceed to disconnect the system and deflate the cuff for re-intubation (refer to: Disconnection).
- **ETT/TT pilot valve failure.** Although very unlikely, prolonged connection to Venner PneuX TSM™ may cause the cuff to deflate when the pilot valve is disconnected from Luer slip of the Venner PneuX™ Extension Tube. Proceed to disconnect the system, (refer to: Disconnection) and reconnect with a new ETT/TT (refer to: Connection to Venner PneuX TSM™).

Luminal occlusion

As with all tracheal tubes, luminal occlusion can occur due to a build-up of secretions in the distal tube over time or with the sudden passing of a large mucus plug or blood clot. This complication can be minimised by ensuring adequate humidification. The use of active humidification with the relatively non-stick coating of an airway lumen can assist in reducing the build-up of secretions in the tube.

Adequate humidification such as the use of active humidification is strongly advised in reducing luminal occlusion.

Medical professionals skilled in advanced airway management should be accessible for immediate attention to medical emergencies such as urgent tube exchanges.

Patient transfer

Perform subglottic secretion drainage (refer to: Subglottic secretion drainage) prior to disconnecting the ETT/TT from the Venner PneuX TSM™ before patient transfers (refer to: Disconnection).

The ETT/TT will remain inflated for up to an hour without connecting to the Venner PneuX TSM™. Cuff pressure should be maintained temporarily (at hourly intervals) with a cuff manometer until a new Venner PneuX™ ETT/TT is reconnected to the Venner PneuX TSM™.

3. Warnings and precautions

The Venner PneuX™ ETT/TT must only be used with the Venner PneuX TSM™ and Venner PneuX™ Extension Tube.

An increase or decrease in cuff pressure can occur due to trans-cuff diffusion of gases. The Venner PneuX™ ETT/TT is designed to be used with the Venner PneuX TSM™ or a standard cuff manometer at least hourly to minimise these changes.

The Venner PneuX™ ETT/TT are single use devices. Reuse may cause cross-infection, reduce product reliability and functionality.

The Venner PneuX™ ETT/TT are not intended to be cut.

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

4. Warranty

PneuX Life Systems warrants the single use products to be free from defects in material and workmanship at the time of delivery. PneuX Life Systems' obligation under this warranty is applicable only if purchased directly from PneuX Life Systems or PneuX Life Systems authorised party, for use with Venner PneuX™ products, and provided the Buyer or Customer has complied with the handling, storage and shelf life requirements as specified by PneuX Life Systems.

THE ABOVE WARRANTIES ARE EXCLUSIVE OF, AND IN LIEU OF, ALL OTHER WARRANTIES, WRITTEN OR ORAL, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE. NO IMPLIED STATUTORY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE SHALL APPLY.

5. Symbols used on labelling

	Caution
	Consult Instructions for Use (IFU)
	Do not re-use
	Sterilised using ethylene oxide
	Medical devices
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Not made with natural rubber latex
	Does not contain phthalates
	Keep away from sunlight
	Date of manufacture
	Legal manufacturer (EU) and Manufactured for (US)
	Authorised representative in the European Community
	European Conformity mark Notified Body: BSI Group (2797)
	Use-by date
	Do not use if package is damaged
	Catalogue number
	Batch code
	MR Conditional

6. MRI Safety Information

Non-clinical testing has demonstrated that the Venner PneuX™ ETT/TT 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
- Maximum spatial field gradient of 3,000 Gauss/cm (30 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Controlled Mode)

Under the scan conditions defined above, Venner PneuX™ ETT/TT is expected to produce a maximum temperature rise of less than 3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the device extends approximately 5 mm from Venner PneuX™ ETT/TT when imaged only with a gradient echo pulse sequence and a 3 Tesla MR system.

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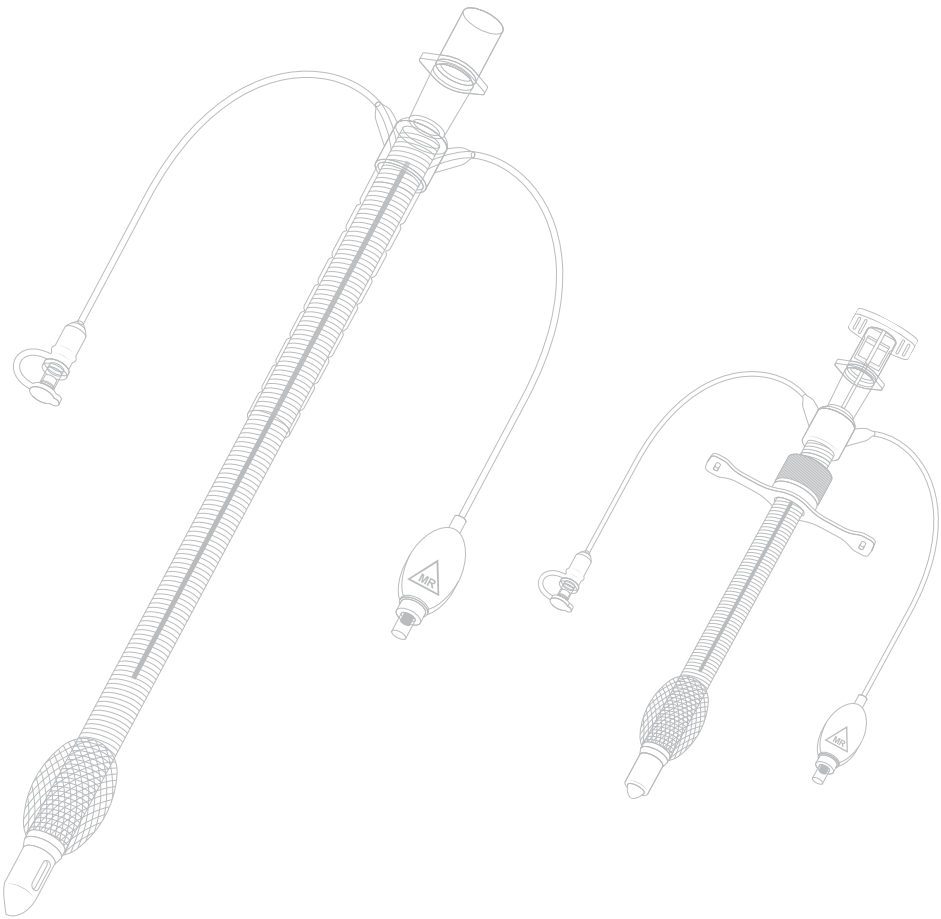

Product is distributed and marketed by:
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