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Venner PneuX™ PDT Introducer Set

Designed exclusively for use with the Venner PneuX™ TT (Tracheostomy Tube).

The below languages are available online at vennermedical.com

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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EC REP

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CE
2797

Product code	Description	Quantity/box
903007	Venner PneuX™ PDT Introducer Set size 7.0mm	10
903008	Venner PneuX™ PDT Introducer Set size 8.0mm	10
903009	Venner PneuX™ PDT Introducer Set size 9.0mm	10

The Venner PneuX™ PDT Introducer sets are designed to be used with the Venner PneuX™ TT (Tracheostomy Tube).

1. Device Description

The Venner PneuX™ PDT (Percutaneous Dilatational Tracheostomy) Introducer Set is an individually packaged Introducer Set for use with the Venner PneuX™ TT (Tracheostomy Tube). The Venner PneuX™ PDT Introducer Set is sterilized by ethylene oxide gas and is for single use only.

The Venner PneuX™ PDT Introducer Set consists of a sealed Tyvek/ film pouch containing a preformed thermoplastic elastomer Introducer, a PTFE coated stainless steel Guidewire, and a tabular thermoplastic elastomer Wire Stiffener. The Guidewire and Wire Stiffener are common components to all sizes of Introducer.

2. Intended Use

The Venner PneuX™ PDT Introducer Set is intended for controlled, elective, subcricoid insertion of a tracheostomy tube in combination with compatible PDT sets. The Venner PneuX™ TT is longer than a conventional tracheostomy tube and so the longer Venner PneuX™ PDT Introducer and Wire Stiffener is required for convenient placement.

3. Contraindications

The Venner PneuX™ PDT Introducer Set is contraindicated when PDT is contraindicated. Follow manufacturer's instructions for the chosen PDT set.

4. Warnings

The warnings for the Venner PneuX™ PDT Introducer Set must be adhered to.

- The Venner PneuX™ PDT Introducer Set is supplied for single use only and it shall not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.
- Only clinicians skilled in advanced airway management who have full expertise in the chosen PDT technique should use the device.

- The Venner PneuX™ PDT Introducer Set is used at clinician's discretion with a variety of wired PDT techniques.
- Aseptic techniques must be strictly adhered to during placement of the device.
- Bronchoscopic guidance is recommended during placement of the device to reduce the likelihood of para-tracheal insertion and to determine the intra-tracheal position of the Guidewire, Introducer and Venner PneuX™ TT.
- Over-insertion of the Venner PneuX™ TT /Introducer should be avoided by partially withdrawing the Introducer once the Venner PneuX™ TT tip is intra-tracheal to prevent the Introducer tip impacting upon the tracheal wall.
- Prior to attempting percutaneous tracheostomy, the patient's airway must be secured with an Endotracheal Tube (ETT).

5. Precautions

- Do not use if the package has been previously opened or damaged.
- The Venner PneuX™ PDT Introducer Set is intended for use by clinicians skilled in percutaneous tracheostomy techniques. Standard techniques for percutaneous placement of tracheostomy tubes should be employed.
- Maintain safety positioning marks of Guidewire, Wire Stiffener and Introducer during dilating procedure to prevent trauma to posterior wall of the trachea.
- The Venner PneuX™ TT should fit securely to the Introducer for insertion. The Introducer should extend 2cm only beyond the Tracheostomy Tube tip during insertion.
- Generous lubrication to the surface of the Introducer and outer Tracheostomy Tube with a water soluble lubricant will enhance fit and placement of the Tracheostomy Tube.
- The Venner PneuX™ PDT Introducer is designed to be inserted within a Venner PneuX™ TT only. The Venner PneuX™ PDT Introducer should not be used for creation of a stoma.

6. Preperations for Use

1. Following the Venner PneuX™ ETT/TT IFU, test the cuff and valve integrity.
2. Using a sterile water soluble lubricant, generously lubricate the surface of the appropriately sized Introducer and load the Venner PneuX™ TT onto the Introducer. Ensure that the Venner PneuX™ TT's tip is positioned approximately 2cm away from the distal Introducer tip. The Venner PneuX™ TT should fit securely on the Introducer. Ensure that the cuff is completely deflated. Thoroughly lubricate intra-tracheal portion of the Venner PneuX™ TT assembly.

7. Procedure

1. The clinician should have clinical expertise and familiarity with the PDT technique chosen. This would normally be a serial dilator or single-step dilator technique.

2. Check compatibility of the components of the Venner PneuX™ PDT Introducer Set with the PDT kit chosen on the sterile trolley prior to starting the procedure. The clinician should satisfy themselves that they have the clinical skills to use the Venner PneuX™ PDT Introducer Set with their chosen PDT technique.

3. Set the Venner PneuX™ TT adjustable flange to the estimated required length and secure by tightening as per the Venner PneuX™ TT IFU instructions.

4. Check that the lubricated Venner PneuX™ PDT Introducer, Wire Stiffener, Guidewire and Venner PneuX™ TT slide freely upon one another.

5. Following the creation of a suitably sized stoma using a PDT kit, the Venner PneuX™ PDT Introducer, Wire Stiffener and Venner PneuX™ TT can be passed along the Guidewire.
Slightly over-dilate the tracheal access site to a size appropriate for passage of the intended Tracheostomy Tube.
(Over-dilation will allow easier passage of the Venner PneuX™ TT into the trachea).

6. To properly align the Venner PneuX™ PDT Introducer on the Guidewire/ Stiffener assembly, position the proximal end of the Introducer at the positioning mark on the Wire Stiffener. This will ensure that the distal tip of the Introducer is properly positioned at the safety ridge on the Wire Stiffener to prevent possible trauma to the posterior tracheal wall during introduction.

7. The Venner PneuX™ PDT Introducer is therefore assembled to the safety ridge on the Wire Stiffener. The Introducer tip being 2cm beyond the tip of the Venner PneuX™ TT.

8. Advance the Guidewire, Wire Stiffener, Introducer and Venner PneuX™ TT as a unit into trachea.

9. Over-insertion of the longer Venner PneuX™ PDT Introducer should be avoided by withdrawing the Introducer into the Venner PneuX™ TT once the Venner PneuX™ TT's tip is intra-tracheal (As guided by bronchoscopic visualisation).

10. The assembly should be directed perpendicular to the axis of the trachea during insertion for uniform dilation between tracheal cartilages. Once the Venner PneuX™ TT is within the tracheal lumen, the assembly may be directed caudad.

11. Remove the Introducer, Wire Stiffener and Guidewire, leaving the Venner PneuX™ TT in place.

12. Advance the Venner PneuX™ TT to its adjustable flange: at this point, the bronchoscope should be inserted into the Venner PneuX™ TT to confirm correct placement and the tube length can be adjusted at the flange as per clinical requirements.

13. Connect the Venner PneuX™ TT to the ventilator, inflate the cuff and remove the ETT. CAUTION: Prior to complete removal of of the Endotracheal Tube, test for adequate ventilation through Tracheostomy Tube and that the capnography trace is normal.

14. Perform suction to determine if any significant bleeding or possible obstruction exists that has not been noted to this point.

15. Chest radiography should be used to confirm optimal position.

8. Manufacturer's 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 a PneuX Life Systems authorised party, for use with Venner PneuXTM 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.

9. Symbols Used On Labelling

	Caution
	Consult instructions for use (IFU)
	Do not re-use
	Sterilised using ethylene oxide
	Single sterile barrier system
	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
	This product 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

Product is distributed
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