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Venner PneuX™ ETT Stylet

Designed exclusively for use with the Venner PneuX™ ETT (Endotracheal Tube).

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es	Instrucciones de uso
fr	Mode d'emploi
it	Istruzioni per l'uso
pt	Instruções de utilização

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Only Venner PneuX™ ETT stylet is to be used with the Venner PneuX ™ ETT (Endotracheal Tube).

1. Device Description

The Venner PneuX™ ETT Stylet is an individually packaged stylet for use with the Venner PneuX™ ETT (Endotracheal Tube). The Venner PneuX™ ETT Stylet is sterilized by ethylene oxide gas and is for single use only.

The Venner PneuX™ ETT Stylet consists of a sealed Tyvek/ Film pouch containing a preformed polyethylene coated malleable aluminum stylet, with a curved proximal tip that hooks over the end of the universal connector to prevent the distal stylet tip from extending beyond the tip of the Venner PneuX™ ETT. Single use available in one standard length appropriate for different tube sizes.

Product code	Description	Quantity/box
903011	Venner PneuX™ ETT Stylet size 4.7 mm 14 Fr	10

2. Intended Use

The Venner Pneux™ ETT Stylet is intended for use as an introducer for the Venner PneuX™ ETT (Endotracheal Tube).
This product cannot be used as a stand-alone device and is specifically designed for aiding the guidance and introduction of a Venner PneuX™ ETT into the trachea.
Venner PneuX™ ETT stylet is a device that allows the Venner PneuX™ ETT to be stiffened and the shape moulded as desired.

3. Contraindications

The Venner PneuX™ ETT Stylet is contraindicated when the use of a stylet is contraindicated. Follow manufacturer's instructions for the chosen stylet.

4. Warnings

The warnings for the Venner PneuX™ ETT used must be adhered to.

- The Venner PneuX™ ETT Stylet 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 should use the device.
- The Venner PneuX™ ETT stylet is used at the clinician's discretion with a variety of wired stylet techniques.
- Aseptic techniques must be strictly adhered to during placement of the device.
- If a stylet is used for video laryngoscopy, different conformations may be optimal depending on the type of video laryngoscope/ blade.

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- Traditional arcuate shaped stylets/ ETTs may obscure the view of the Venner PneuX™ ETT tip on insertion and cause the tip of the Venner PneuX™ ETT to abut against the inner surface of the anterior trachea once the Venner PneuX™ ETT has passed through the cords.

5. Precautions | Complications

- Do not use if the package has been previously opened or damaged.
- The Venner PneuX™ ETT stylet is intended for use by clinicians skilled in stylet endotracheal techniques.
- The Venner PneuX™ ETT Stylet is designed to be inserted within a Venner PneuX™ ETT only.
- Trauma due to protrusion of the stylet tip beyond the end of the Venner PneuX™ ETT.
- Inadvertent removal of the Venner PneuX™ ETT when removing the stylet.

6. Preparation For Use

1. Following the Venner PneuX™ ETT/TT IFU, test the cuff and valve integrity.
2. Lubricate the stylet prior to use.

7. Procedure

1. The clinician should have clinical expertise and familiarity with the stylet technique chosen.
2. Lubricate stylet with water soluble gel.
3. Insert stylet into Venner PneuX™ ETT. (Stylet should not extend beyond the tip).
4. Once the stylet is in the correct position within the Venner PneuX™ ETT, bend the top of the stylet to anchor in situ.
5. Bend the stylet into the desired shape. (Optimal shape for intubation direct laryngoscopy is 'straight-to-the-cuff' with a 'hockey stick' bend at the cuff of no more than 35 degrees).
6. Venner PneuX™ ETT is inserted from the right side of the patient's mouth to maximise your view and provide optimal control of the position of the tip of the endotracheal tube.

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 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.

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
and marketed by:
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and its appointed representatives

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