



EN Instructions for use Tritube®

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Product name

tritube 

Tube length

40 cm

OD = outer diameter

4.4 mm

Cuff diameter



Dead space

1.9 mL

Does not contain
natural rubber latex



Read these instructions for use prior to using the product. Refer to the product website <https://www.ventinova-medical.com/products/tritube> for further information and training materials related to this product.

Intended use

Tritube is intended to be used for obtaining endotracheal access to the airway for ventilating a patient with an Expiratory Ventilation Assistance (EVA®) device.

Operator

Tritube must be applied by, or under supervision of, medical personnel trained and experienced in airway management.

Patient group

Adults

Contraindications

Use of Tritube in procedures, which will involve the use of a laser or an electrosurgical active electrode in the immediate area of the device, is contraindicated.

Potential complications

Potential complications include (but are not limited to) tracheal mucosal damage, necrosis and ulceration, damaged ciliary motility, reduced circulation in tracheal mucosa.

Product description

Tritube is a small bore cuffed endotracheal tube made of polyurethane. Tritube has 3 lumen: a main "ventilation lumen", a "cuff lumen" and a "pressure measurement lumen". The "ventilation lumen", having also a Murphy eye, is intended to be connected to devices with EVA technology by the **orange** Luer connector.

The "cuff lumen" is used to inflate the cuff at the distal end to seal off the trachea. A self-sealing valve prevents (passive) deflation, and a pilot balloon at the proximal end confirms inflation and allows cuff pressure measurement / monitoring by a cuff pressure gauge.

The "pressure measurement lumen" can be connected to a pressure monitoring device by the **transparent grey** female EVA-barb connector, in order to measure intratracheal pressures. Tritube has centimeter markings to facilitate accurate depth of placement. The tube tip is rounded to avoid tracheal lesions. A stainless steel malleable stylet is provided within Tritube to facilitate intubation.

Packaging

- The package contains one Tritube.
- It is packed in a peel-open package sterilized by use of ethylene oxide.

- Tritube is sterile as long as the packaging is undamaged, unopened and within its expiry date.
- Do not use Tritube if any doubt exists on the integrity of the package.
- Store the packaged product in a dry place.
- Avoid extended exposure to direct sun light.

Required additional material

- Expiratory Ventilation Assistance (EVA) ventilation device.
- Pressure measuring device to monitor intratracheal pressure.
- Cuff pressure gauge to inflate cuff and to measure/monitor the cuff pressure.
- Syringe to deflate cuff
- Optional: water soluble lubricating jelly facilitating intubation and improving sealing of the trachea by the cuff.
- Syringe with saline to flush ventilation or pressure lumen.

Warnings and precautions

- Use Tritube only in combination with ventilators with EVA technology, while permanently monitoring the intratracheal pressure.
- For specific risks ventilating with active expiration, refer to the instructions for use of the ventilator.
- Do not overinflate the cuff (<30 cm H₂O) to avoid complications, while maintaining an adequate seal of the trachea.
- Do not use Tritube in combination with high energy procedures, because it is potentially flammable in the presence of lasers and electrical cautery.
- Do not reinsert the stylet into Tritube once the stylet is withdrawn. It may damage or puncture the tube wall and / or the inside of Tritube.
- Remove stylet before nasotracheal placement of Tritube.
- Fully deflate the cuff, evidenced by a collapsed pilot balloon, during weaning of a patient (or applying

weaning mode of the ventilator). Otherwise the trachea might still be obstructed, potentially leading to extremely high airway pressures causing life threatening barotrauma and circulatory deterioration.

- Fully deflate the cuff, evidenced by a collapsed pilot balloon, before repositioning or removal of the tube to avoid tracheal damage. Verify correct (depth of) placement after each repositioning.
- Rigid or sharp anatomical structures in the intubation route (e.g. teeth) or intubating tools (e.g. Magill forceps) might damage the cuff during intubation. If the cuff is damaged, Tritube should not be used (any more).
- If lubricating jelly is used, apply this (according to the manufacturer's protocol) only to the cuff, but avoid the Murphy eye and opening of the pressure measurement lumen at the distal tip of Tritube. Excessive amounts of the lubricant may dry on the inner surface of the ventilation lumen or pressure measurement lumen of the tube resulting in either a lubricant plug or a clear film partially or even totally blocking the pressure measurement or ventilation lumen.
- Do not connect a sidestream capnometer to the pressure measurement lumen, because this may affect the function of the lumen (e.g. unreliable pressure measurement).
- In case of alternative ventilation by means of a face or laryngeal mask fully deflate the cuff and optionally remove Tritube before placement of a face or laryngeal mask.
- Be aware that the device may be dislodged due to coughing.
- Remove secretions on the cuff prior to deflating it.

Instructions for use

- 1.** Remove the sterile Tritube from its protective package.
- 2.** Test the cuff, pilot balloon and its valve by inflation prior to use: Insert a Luer tip syringe into

or connect a cuff pressure gauge to the cuff inflation valve housing and inject air to fully inflate the cuff. In case of an obstruction in the ventilation or pressure lumen of Tritube, flush lumen with saline and/or air.

3. After testing for leakage and proper function, completely evacuate the air from the cuff.
4. Visually assess the larynx and estimate the required length and shape of Tritube to assure subglottic placement.
5. Apply the appropriate shape by malleate Tritube with the stylet inside. In case of nasotracheal intubation the stylet should be removed from Tritube before placement.
6. Lubrication of the cuff is advised to facilitate intubation, lowering the risk of damaging the cuff during intubation and to increase its sealing performance (see Table 1). Avoid the lateral openings at the distal end of the tube.
7. Intubate the patient following currently accepted medical techniques for intubation when using a stylet (in case of orotracheal intubation) or conventional intubation (in case of nasotracheal intubation) with consideration given to the specific cuff-related **Warnings and Precautions** stated in this product manual.
8. After intubation inflate the cuff using a cuff pressure gauge. Cuff pressures should not exceed 30 cm H₂O to avoid complications while maintaining an adequate seal of the trachea. In case of weaning of a patient (or applying weaning mode of the ventilator) DO NOT inflate the cuff.
9. Cuff pressure should be closely monitored while the patient is intubated. Any deviation from the desired cuff pressure should be investigated and corrected immediately.
10. Connect the **transparent grey** female EVA-barb connector of the pressure measurement lumen to a pressure measuring device.

11. If Tritube is not connected to a device with an automated purge function, purge the pressure measurement lumen with a syringe before starting ventilation to exclude any obstruction by lubricant if applied.
12. Connect the **orange** Luer connector of the ventilation lumen to an EVA ventilation device.
13. Confirm endotracheal position of Tritube using standard methods (e.g. capnography).
14. Prior to extubation, repositioning of the tube or switching to another mode of operation of the ventilator that requires an open airway: remove secretions by suction, deflate the cuff completely by inserting a syringe into the valve housing and removing gas until a definite vacuum is noted in the syringe and the pilot balloon is collapsed.
15. Extubate the patient following currently accepted medical techniques.
16. Follow hospital procedures for correct disposal of the tube.

Table 1 The performance information shown below was collected using a bench test that is intended to provide a comparison of the sealing characteristics of tracheal tube cuffs in a laboratory setting only. The bench test is not configured or intended to predict performance in the clinical setting.

Tracheal tube cuff performance for Tritube [per ISO 5361 method]

Lubricant [#1]	Cuff pressure [cmH ₂ O]	Minimum trachea diameter: 16 mm		Maximum trachea diameter: 24 mm	
		Leakage rate range [mL/h]		Leakage rate range [mL/h]	
		50th percentile	90th percentile	50th percentile	90th percentile
With	25	0	6	0	9
Without	25	27	121	18	99

[#1] K-Y® Lubricating Jelly Sterile (water-soluble).

Each time 0.8 g ± 0.2 g used.

References

Helpful references for more detailed information of cuff pressures and / or tracheal tube adverse reactions include the following:

- Blunt MC, Young PJ, Patil A and Haddock A.
Gel lubrication of the tracheal tube cuff reduces pulmonary aspiration.
Anesthesiology. 2001 Aug;95(2):377-81
- Dullenkopf A, Gerber A and Weiss M.
Fluid leakage past tracheal tube cuffs: evaluation of the new Microcuff endotracheal tube.
Intensive Care Med. 2003 Oct;29(10):1849-53
- Sengupta P, Sessler DI, Maglinger P, Wells S, Vogt A, Durrani J and Wadhwa A.
Endotracheal tube cuff pressure in three hospitals, and the volume required to produce an appropriate cuff pressure.
BMC Anesthesiol. 2004 Nov 29;4(1):8
- Spiegel JE.
Endotracheal tube cuffs: Design and function.
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