INSTRUCTION FOR USE

Product Name	:	ENDOTRACHEAL TUBE
Brand Name	:	Ultramed Endotracheal Tube.
Manufacturer's Name	:	Ultra for Medical Products (ULTRAMED) Co. (U.M.I.C) S.A.E
Manufacturer's Address	:	Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt.

- Description of the Device:

- Endotracheal tubes are manufactured from polyvinylchloride (PVC), which provides optimal stiffness for ease of intubation, becomes more pliable at body, and incorporates a radiopaque line to allow visualization on radiographs for proper positioning.
- The endotracheal tube diameter marked on its surface. The endotracheal tube size (" 6.0 tube") refers to its internal diameter in millimeters (mm). The ETT will typically list both the inner and outer diameter of the tube.
- It is marked with "Length Marking "in centimeters, which indicate the distance to the distal tip. To monitor the endotracheal tube position and detect if it has moved outwards or further down into a bronchus. Also It is marked with "glottic depth mark(s)"is indicator on the tracheal tube to assist in determining the tip insertion depth beyond the vocal cords
- It has a Beveled Tip at the distal end, to make it easier to pass through the vocal cords and to give you a better vision ahead of the tip, endotracheal tubes have a "slant" called a bevel.
- It has a Murphy Eye: The Murphy Eye is a small hole located near the end of the tube on the side opposite to the bevel. This secondary opening helps prevent the tube from getting blocked. If the main opening at the tip of the tube becomes obstructed due to contact with the tracheal mucosa, or by a mucous plug or clot, the Murphy Eye ensures that air can still flow through the tube, providing an additional safeguard.
- The cuffed type of endotracheal tube has an inflatable cuff located at the patient end of the tube. When inflated, the cuff forms a seal against the tracheal wall, ensuring that air is delivered directly into the lungs without leaking around the tube. It also helps prevent secretions from entering the lungs, thereby reducing the risk of aspiration and infection. After intubation, the cuff is inflated with air by attaching a syringe to the pilot balloon. The pilot balloon is connected to the cuff by a thin tube known as the inflation line. As pressurized air is introduced via the syringe, both the cuff and the pilot balloon inflate. Once adequate inflation is achieved, the syringe is removed. Air does not leak because a non-return valve within the pilot balloon maintains cuff pressure. The appearance of the pilot balloon provides visual confirmation of cuff status: an inflated pilot balloon indicates cuff inflation after endotracheal intubation, while a deflated balloon indicates cuff deflation prior to extubation. If the cuff leaks—for example, due to surgical damage during procedures such as thyroidectomy—the pilot balloon will collapse.
- The valve which is equipped in the pilot balloon fulfills the requirements of ISO 80369-7.
- Tracheal tube cuffs are designed to seal the trachea using **high-volume, low-pressure cuffs** to reduce the risk of hypoventilation and aspiration while limiting damage to the tracheal mucosa.
- The 15 mm conical endotracheal tube connector provides standardized compatibility with ventilating devices, including Anaesthetic Breathing Systems (ABS) and Ventilator Breathing Systems (VBS). It ensures a secure connection and facilitates the controlled delivery of oxygen and other medical gases to the lungs.
- The 15 mm conical endotracheal tube connector fulfills the requirements of ISO 5356-1.

- Reinforced and cuffed endotracheal tubes contain metallic components and are classified as MR Unsafe. Uncuffed endotracheal tubes without metallic components are MR Safe.
- The Endotracheal tube designs fulfil the requirements of ISO 5361.
- Tracheal tubes are intended to be inserted orally or nasally through the larynx into the trachea to convey drugs, gases and vapours to and from a patient's lungs during spontaneous, assisted or controlled ventilation for short durations.
- Where Proper designation "Oral"," Nasal" or "Oral/Nasal "is printed on the tracheal tube.
  ***Ref:** According to ISO 5361:2023
- ETTs are usually removed after a procedure or improvement of an acute illness. ETTs cannot be used indefinitely and should be removed within 14 days. if ventilation is required for longer than 14 days, a tracheostomy is needed.

- **Available Types of Endotracheal Tube**
- **Endotracheal tube with/without Cuff**

  Is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is also available with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases. It is intended for short term use.

- **Reinforced Endotracheal Tube Cuffed**
- Is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through **the patient's nose or mouth** in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases.
- **The reinforced endotracheal tube is specifically designed for use in specialized medical procedures, such as neurosurgical procedures and head and neck surgeries. our reinforced tracheal tube includes a spiral wire embedded in the tube's structure. This unique design provides effective resistance to kinking or Occluding, ensuring that airflow remains unobstructed during critical procedures.**
- Additionally, their design allows for easier manipulation without compromising airflow, which is critical during intricate head and neck operations.
- In procedures where neck movement is expected, using a reinforced endotracheal tube significantly improves patient safety and ensures that ventilation remains consistent throughout the surgery. The cuff reduces the chances of accidental dislodgment.

- **Oral Preformed Endotracheal Tube with/without cuff**

  Is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through **the patient's mouth** in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is also available with a cuff which make seal between cuff and tracheal wall after inflation to prevent leakage of gases. Also the tube is preformed **to meet the specific requirements of patients undergoing head, nasal. ophthalmic and facial surgery**. It is intended for short term use

❖ **Nasal Preformed Endotracheal Tube with/without cuff**

Is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through **the patient's nose** in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube may be provided with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases. **The tube is preformed to meet the specific requirements of patients undergoing facio-maxillary surgery in oral passage. It is intended for short term use.**

Available sizes:

- Cuffed Endotracheal tube [from 2 to 9]
- Uncuffed Endotracheal tube [from 2 to 9]
- Reinforced Endotracheal tube [from 2 to 9]
- Oral Preformed Endotracheal Tube cuffed [from 2 to 9]
- Oral Preformed Endotracheal Tube Uncuffed [from 2 to 9]
- Nasal Preformed Endotracheal Tube cuffed [from 2 to 9]
- Nasal Preformed Endotracheal Tube Uncuffed [from 2 to 9]

❖ This product is for single use as it marked on its surface by symbol for "single use only"
❖ Endotracheal Tube individually packed in a Peel Pouch
❖ The product is sterilized using EO (Ethylene Oxide)

Description of the packaging:

Unit Container:

❖ The unit container is made of Medical Pouches that consists of:
Poly Ethylene Blister film and medical paper.
❖ Unit Package maintains a sterility barrier with its seal.
❖ The integrity of package does not compromise due to normal handling, storage, sterilization or transportation.
❖ Unit package should open reliably without tearing and particulate matter generation.

Type: Endotracheal Tube Cuffed and Uncuffed & Reinforced			Quantity in the box	Quantity inside Carton
Sizes	From 2	To 2.5	80	10
	From 3	To 4	50	10
	From 4.5	To 5.5	40	10
	From 6	To 6.5	20	18
	From 7	To 9	15	18

Type: Preformed Endotracheal Tube With / Without cuff			Quantity in the box	Quantity inside Carton
Sizes	From 2	To 5.5	20	8
	From 6	To 9	10	8

Material Used:

- **Poly Vinyl Chloride [P.V.C DEHP free]**
- **Polypropylene [P.P]**

Intended purpose:

- Tracheal tubes are intended to be inserted orally or nasally through the larynx into the trachea, they are used to establish a temporary artificial airway to convey Drugs, gases and vapours to and from a patient's lungs during spontaneous, assisted or controlled ventilation for short durations in the medical department for anesthesia and oxygen delivery. They also allow the passage of a suction catheter for removal of secretions and to prevent aspiration of fluids into the lungs.

Variants:

Code	**Item**
4006-2	Endotracheal tube Cuffed Size 2
4006-2.5	Endotracheal tube Cuffed Size 2.5
4006 – 3	Endotracheal tube Cuffed Size 3
4006 – 3.5	Endotracheal tube Cuffed Size 3.5
4006 – 4	Endotracheal tube Cuffed Size 4
4006 - 4.5	Endotracheal tube Cuffed Size 4.5
4006 – 5	Endotracheal tube Cuffed Size 5
4006 - 5.5	Endotracheal tube Cuffed Size 5.5
4006 – 6	Endotracheal tube Cuffed Size 6
4006 - 6.5	Endotracheal tube Cuffed Size 6.5
4006 – 7	Endotracheal tube Cuffed Size 7
4006 - 7.5	Endotracheal tube Cuffed Size 7.5
4006 – 8	Endotracheal tube Cuffed Size 8
4006-8.5	Endotracheal tube Cuffed Size 8.5
4006-9	Endotracheal tube Cuffed Size 9
4005 – 2	Endotracheal tube Uncuffed Size 2
4005 - 2.5	Endotracheal tube Uncuffed Size 2.5
4005 – 3	Endotracheal tube Uncuffed Size 3
4005 - 3.5	Endotracheal tube Uncuffed Size 3.5
4005 – 4	Endotracheal tube Uncuffed Size 4
4005 - 4.5	Endotracheal tube Uncuffed Size 4.5
4005 – 5	Endotracheal tube Uncuffed Size 5
4005 - 5.5	Endotracheal tube Uncuffed Size 5.5
4005 – 6	Endotracheal tube Uncuffed Size 6
4005 - 6.5	Endotracheal tube Uncuffed Size 6.5
4005 – 7	Endotracheal tube Uncuffed Size 7
4005 – 7.5	Endotracheal tube Uncuffed Size 7.5
4005 - 8	Endotracheal tube Uncuffed Size 8
4005 – 8.5	Endotracheal tube Uncuffed Size 8.5
4005-9	Endotracheal tube Uncuffed Size 9
4007-2	Endotracheal tube reinforced Cuffed size 2
4007-2.5	Endotracheal tube reinforced Cuffed size 2.5
4007-3	Endotracheal tube reinforced Cuffed size 3
4007-3.5	Endotracheal tube reinforced Cuffed size 3.5
4007-4	Endotracheal tube reinforced Cuffed size 4
4007-4.5	Endotracheal tube reinforced Cuffed size 4.5
4007-5	Endotracheal tube reinforced Cuffed size 5

Code	**Item**
4007-5.5	Endotracheal tube reinforced Cuffed size 5.5
4007-6	Endotracheal tube reinforced Cuffed size 6
4007-6.5	Endotracheal tube reinforced Cuffed size 6.5
4007-7	Endotracheal tube reinforced Cuffed size 7
4007-7.5	Endotracheal tube reinforced Cuffed size 7.5
4007-8	Endotracheal tube reinforced Cuffed size 8
4007-8.5	Endotracheal tube reinforced Cuffed 8.5
4007-9	Endotracheal tube reinforced Cuffed 9
4009-2/PN	Endotracheal Tube Preformed 2.0 Cuffed (Nasal)
4009-2.5/PN	Endotracheal Tube Preformed 2.5 Cuffed (Nasal)
4009-3/PN	Endotracheal Tube Preformed 3.0 Cuffed (Nasal)
4009-3.5/PN	Endotracheal Tube Preformed 3.5 Cuffed (Nasal)
4009-4/PN	Endotracheal Tube Preformed 4.0 Cuffed (Nasal)
4009-4.5/PN	Endotracheal Tube Preformed 4.5 Cuffed (Nasal)
4009-5/PN	Endotracheal Tube Preformed 5.0 Cuffed (Nasal)
4009-5.5/PN	Endotracheal Tube Preformed 5.5 Cuffed (Nasal)
4009-6/PN	Endotracheal Tube Preformed 6.0 Cuffed (Nasal)
4009-6.5/PN	Endotracheal Tube Preformed 6.5 Cuffed (Nasal)
4009-7/PN	Endotracheal Tube Preformed 7.0 Cuffed (Nasal)
4009-7.5/PN	Endotracheal Tube Preformed 7.5 Cuffed (Nasal)
4009-8/PN	Endotracheal Tube Preformed 8.0 Cuffed (Nasal)
4009-8.5/PN	Endotracheal Tube Preformed 8.5 Cuffed (Nasal)
4009-9/PN	Endotracheal Tube Preformed 9.0 Cuffed (Nasal)
4009-2/PO	Endotracheal Tube Preformed 2.0 Cuffed (Oral)
4009-2.5/PO	Endotracheal Tube Preformed 2.5 Cuffed (Oral)
4009-3/PO	Endotracheal Tube Preformed 3.0 Cuffed (Oral)
4009-3.5/PO	Endotracheal Tube Preformed 3.5 Cuffed (Oral)
4009-4/PO	Endotracheal Tube Preformed 4.0 Cuffed (Oral)
4009-4.5/PO	Endotracheal Tube Preformed 4.5 Cuffed (Oral)
4009-5/PO	Endotracheal Tube Preformed 5.0 Cuffed (Oral)
4009-5.5/PO	Endotracheal Tube Preformed 5.5 Cuffed (Oral)
4009-6/PO	Endotracheal Tube Preformed 6.0 Cuffed (Oral)
4009-6.5/PO	Endotracheal Tube Preformed 6.5 Cuffed (Oral)
4009-7/PO	Endotracheal Tube Preformed 7.0 Cuffed (Oral)
4009-7.5/PO	Endotracheal Tube Preformed 7.5 Cuffed (Oral)
4009-8/PO	Endotracheal Tube Preformed 8.0 Cuffed (Oral)
4009-8.5/PO	Endotracheal Tube Preformed 8.5 Cuffed (Oral)
4009-9/PO	Endotracheal Tube Preformed 9.0 Cuffed (Oral)
4010-2.0/PN	Endotracheal Tube Preformed 2.0 UNCuffed (Nasal)
4010-2.5/PN	Endotracheal Tube Preformed 2.5 UNCuffed (Nasal)
4010-3/PN	Endotracheal Tube Preformed 3.0 UNCuffed (Nasal)
4010-3.5/PN	Endotracheal Tube Preformed 3.5 UNCuffed (Nasal)
4010-4/PN	Endotracheal Tube Preformed 4.0 UNCuffed (Nasal)

Code	**Item**
4010-4.5/PN	Endotracheal Tube Preformed 4.5 UNCuffed (Nasal)
4010-5/PN	Endotracheal Tube Preformed 5.0 UNCuffed (Nasal)
4010-5.5/PN	Endotracheal Tube Preformed 5.5 UNCuffed (Nasal)
4010-6/PN	Endotracheal Tube Preformed 6.0 UNCuffed (Nasal)
4010-6.5/PN	Endotracheal Tube Preformed 6.5 UNCuffed (Nasal)
4010-7/PN	Endotracheal Tube Preformed 7.0 UNCuffed (Nasal)
4010-7.5/PN	Endotracheal Tube Preformed 7.5 UNCuffed (Nasal)
4010-8/PN	Endotracheal Tube Preformed 8.0 UNCuffed (Nasal)
4010-8.5/PN	Endotracheal Tube Preformed 8.5 UNCuffed (Nasal)
4010-9/PN	Endotracheal Tube Preformed 9.0 UNCuffed (Nasal)
4010-2/PO	Endotracheal Tube Preformed 2.0 UNCuffed (Oral)
4010-2.5/PO	Endotracheal Tube Preformed 2.5 UNCuffed (Oral)
4010-3/PO	Endotracheal Tube Preformed 3.0 UNCuffed (Oral)
4010-3.5/PO	Endotracheal Tube Preformed 3.5 UNCuffed (Oral)
4010-4/PO	Endotracheal Tube Preformed 4.0 UNCuffed (Oral)
4010-4.5/PO	Endotracheal Tube Preformed 4.5 UNCuffed (Oral)
4010-5/PO	Endotracheal Tube Preformed 5.0 UNCuffed (Oral)
4010-5.5/PO	Endotracheal Tube Preformed 5.5 UNCuffed (Oral)
4010-6/PO	Endotracheal Tube Preformed 6.0 UNCuffed (Oral)
4010-6.5/PO	Endotracheal Tube Preformed 6.5 UNCuffed (Oral)
4010-7/PO	Endotracheal Tube Preformed 7.0 UNCuffed (Oral)
4010-7.5/PO	Endotracheal Tube Preformed 7.5 UNCuffed (Oral)
4010-8/PO	Endotracheal Tube Preformed 8.0 UNCuffed (Oral)
4010-8.5/PO	Endotracheal Tube Preformed 8.5 UNCuffed (Oral)
4010-9/PO	Endotracheal Tube Preformed 9.0 UNCuffed (Oral)

Clinical Indications:

- Patients who cannot breathe spontaneously or need respiratory anesthesia during surgery.
- People who are unconscious
- **Surgery:** When a person is under general anesthesia, the lungs are paralyzed. Intubation allows the tube to be connected to a mechanical ventilator to assist with breathing.
- **Breathing support:** An endotracheal tube can support breathing in people with lung diseases, severe pneumonia, a head injury, collapsed lung, respiratory failure, congestive heart failure, acute respiratory distress syndrome (ARDS), or other conditions that affect breathing.
- **Prevention and management of airway obstruction**: in patients with conditions including neck tumors, external airway compression, or extreme obesity.
- **Airway protection:** An endotracheal tube can prevent the contents of the stomach from getting into the lungs during a massive gastrointestinal bleed, intra-abdominal pressure, frequent vomiting.
- **Delivery of anesthetics:** in surgical settings it enables the administration of anesthetic gases directly to the lung
- **Emergency Situations:** In emergencies such as severe asthma attacks or cardiac arrest, an endotracheal tube is rapidly inserted to secure the airway and assist with ventilation.
- **Critical Care:** Patients with severe illnesses or injuries might need an ETT to ensure they continue to breathe properly.

- **Severe Trauma:** In cases of severe trauma, such as major accidents, intubation may be necessary to maintain an open airway and support breathing.

Conditions for Oral Endotracheal Intubation and not suitable for Nasal Intubation:

- Patients with skull base fracture, nasopharyngeal hemangioma, should not be treated with Endotracheal Tube Nasal Preformed.
- **Severe facial trauma** (e.g., fractures, deformities) of nasal passage
- **Maxillofacial surgery or trauma**: In cases where nasal passage access is compromised
- **Surgical procedures requiring direct access to the airway**: For procedures like those involving the larynx or trachea (e.g., laryngectomy, tracheostomy).
- **Obstructed nasal passages**: Conditions like nasal congestion, septal deviation, nasal polyp, nasal tumor.
- **History of recurrent sinus infections or nasal surgeries**: Patients with extensive nasal surgery history or chronic sinusitis may have narrow or scarred nasal passages that make intubation difficult.
- **Recent nasal surgery or injury**: Oral intubation is indicated when there has been recent trauma or surgery to the nasal passages that might render nasal intubation unsafe.
- **Coagulopathy or bleeding disorders**: In patients with bleeding disorders or those on anticoagulant therapy, nasal intubation can be more risky due to the potential for epistaxis (nose bleeds) and other complications.
- **Severe upper respiratory infections or sinusitis**: In patients with active sinus infections, nasal intubation may risk worsening infection or spreading it to other areas, making oral intubation safer.

Conditions for Nasal Endotracheal Intubation and not suitable for Oral Intubation:

- **Severe facial injuries**: In patients with fractures or injuries to the facial bones (e.g., maxillary, mandibular fractures), oral intubation may be difficult or impossible.
- **Oral surgery**: In patients undergoing dental or oral procedures.
- **Obstructions or Tumors in the Oral Cavity or Pharynx.**
- **Tumors or growths in the mouth or throat**: Conditions such as oropharyngeal tumors, masses, or severe inflammation (like epiglottitis or peritonsillar abscess) can obstruct the oral airway,
- **Severe bleeding in the oral cavity**.
- Patient with high risk of aspiration as **gastroesophageal reflux** diseases to reduce risk of aspiration

Contraindications:

- Do not use if Known hypersensitivity to any material used in the device.
- Do not use with patients who have laryngeal edema, acute inflammation of the airway, pressure of airway by thoracic aorta, severe hemorrhage, cervical spine injury.
- Do not use this product in laser surgery.
- Do not use with flammable anesthetic gases or agents, laser, electrosurgical equipment.
- Do not use Cuffed or Reinforced Endotracheal Tube in the MRI environment.

Device Limitation:

- Do not use the endotracheal tube beyond 14 days, as it is intended for short-term use.
- Do not use a non-reinforced endotracheal tube alone without a bite block in cases where the patient may bite down and flatten the tracheal tube, resulting in obstruction.
- Do not rely on the endotracheal tube for suctioning, as it is not designed with an integrated suction port and requires the use of an external suction catheter.

- Do not use the endotracheal tube for purposes other than tracheal intubation and ventilation support, such as drug delivery outside the airway or for surgical procedures not involving airway management.
- Do not use the endotracheal tube for fluid delivery, as it is intended for delivering oxygen or anesthetic gases.

Patient Target Group:

- It is used in all ages [new-born, children, adolescents and Adult]
- It is used for males and females.
- The correct size of an ET tube varies between children and adults. For adults, tube size is usually based on gender and body size. Adult males typically need larger tubes (around 7.5-8.5 mm in diameter), while females need slightly smaller tubes (around 7.0-8.0 mm).
- The age-based formula presented by Cole [ID (mm) = (age/4) + 4.0] has long been used to select the appropriate ETT size in children. This formula is suitable for uncuffed ETTs
- When estimating cuffed ETT size using an age-based formula, Duracher's formula [ID (mm) = (age/4) + 3.5] is more accurate. However, a tube 0.5 mm larger or smaller than the calculated size should always be possible to use.
- Some articles indicate the formula by **height** is most **suitable** for size **selection** of nasotracheal tubes in **healthy** children

Formulas: weight (weight [kg]/10 + 3.5), or height (2 + height [cm]/30)

Application site in the body:

- Tracheal tubes are intended to be inserted orally or nasally through the larynx into the trachea.

Replacement Frequency:

- The device should be replaced immediately if contamination or balloon dysfunction is suspected.
- ETTs are usually removed after a procedure or improvement of an acute illness. ETTs cannot be used indefinitely and should be removed within 14 days. if ventilation is required for longer than 14 days, a tracheostomy is needed.

Intended User:

- To be Intubated by an expert qualified medical professional, Skilled or Trained Personnel ***(In-Charge)***

Clinical benefits:

- The endotracheal tube maintains airway patency by forming a conduit between the upper airway and trachea, allowing assisted or controlled ventilation and oxygen delivery, with optional cuff inflation to seal the trachea and minimize aspiration risk.

Use Environment:

- Hospital, Emergency Room, Critical care room, respiratory care departments, and anesthesiology departments.

Life time of device:

- The maximum recommended duration of use is 14 days. Prolonged ventilation beyond this period may require a tracheostomy, as determined by the clinician.

Sterility status and Method of sterilization:

- The Endotracheal Tube is supplied in sterile state and sterilized using ethylene oxide.

Information on medical device intended to be used with other devices:

- The endotracheal tube is intended for use with anesthetic breathing systems (ABS) and ventilator breathing systems (VBS) via a standardized 15 mm connector in accordance with ISO 5356-1.

- Cuffed endotracheal tubes include a pilot balloon equipped with a non-return valve compliant with ISO 80369-7, permitting controlled inflation and deflation of the cuff with a syringe.
- A stylet may be used to facilitate manipulation and passage of the tube through the larynx.
- A suction catheter may be used through the lumen of the endotracheal tube for airway suctioning when clinically indicated.

Performance Characteristics:

- For use in both Oral & Nasal intubations.
- Made of special thermosensitive material readily conforming to body curvatures at body temperature.
- High volume low pressure cuff provides an effective low pressure seal.
- Atraumatic Soft rounded beveled tip.
- Soft rounded murphy eye.
- Accurate depth mark.
- Reinforced with stainless steel coil to assure continuous non-blockage of air in the tube during procedure
- X-ray opaque line on the tube to facilitate easy location of tube.
- Standard 15 mm connector

Risks Associated with reuse

- Re-use of the device may create a potential risk to the patient, including contamination and/or impairment of the device function.

Instruction for Use:

- ***preparation***
  1- Evaluate the patient's airway anatomy and clinical condition
  2- Choose the appropriate sizes of the Endotracheal tube according to the patient's age, gender and other specific conditions.
  3- Evaluate all necessary equipment is available (laryngoscope, stylet, ventilator, ETT tube of appropriate size syringe, Suction Catheter, tape, lubricants, etc.)
  4- Before an endotracheal tube is placed, ensure that all jewelry is removed, especially tongue piercings.
  5- An endotracheal tube is often placed when a patient is unconscious. If a patient is conscious, medications are used to ease anxiety while the tube is placed and until it is removed.
  6- Check the packing carefully, if packing is found damaged, torn or pierced, discard the piece.
  7- Wash-up and scrub hands and preferably use sterile protective gloves.
  8- Peel the pouch and take out the device aseptically.
  9- Do not use this product unless these checks are fully satisfactory.
  - Check the Expiry Date.
  - Visually check whole device for discoloration, damage and flaws.
  10- Prior to intubation, test the cuff system **[If available]**. Insert a syringe into the valve and inflate the cuff, ensuring it is not overinflated. Check for leaks, cuff herniation, and leakage from the inflation valve. Reinsert the syringe and completely deflate the cuff.
- ***Intubation***
  11- **Optional tube softening for Nasal Intubation** is performed by briefly immersing the endotracheal tube in sterile normal saline at 40 °C ± 1 °C to increase flexibility for easier nasal insertion while maintaining lumen patency. Care should be taken to avoid

overheating to ensure that the structural integrity and functional performance of the tube are not compromised.

12- Positioning

The patient is laid on their back **[supine position]** with their head tilted back slightly. This position helps to open the airway, making it easier for the doctor to insert the tube. The doctor stands at the head of the bed, where they have the best angle to see and access the patient's throat.

13- If lubrication of the endotracheal tube is required, use only water-soluble lubricant, taking care to avoid occluding the tube lumen, and do not use petroleum-based lubricants, as they may damage the cuff or traumatize the patient's trachea.

14- The endotracheal tube is inserted through the nose or through the mouth with the assistance laryngoscope to gently lift the tongue and see the vocal cords, which are the gateway to the trachea. A stylet may be used if difficult intubation is encountered. The doctor carefully guides the ETT past the vocal cords and into the trachea typically 2-4 cm above the carina, a step that requires precision to avoid injury.

15- When it's thought that the endotracheal tube is in the proper location, the doctor listen for bilateral breath sounds over the lungs and absence of sounds over the stomach to make sure that the endotracheal tube was not inadvertently inserted into the esophagus. Other signs that suggest the tube is in the proper position may include seeing chest movement, capnography, observation of patient monitoring parameters,

16- Remove the laryngoscope and stylet while holding the tube in place.

17- After intubation, inflate the cuff **[If available]** using the minimum volume of air required to provide an effective seal.

18- Endotracheal tube placement should be confirmed by viewing the position of the tube tip with a chest radiograph.

19- **Securing the Tube**

The tube is secured with tape to prevent movement. This helps reduce the risk of accidental dislodgement, which could compromise the patient's breathing.

20- **Connecting to a Ventilator Breathing system (VBS) or Anaesthetic Breathing System (ABS)**

The tube is then connected to a ventilator. This machine helps the patient breathe by delivering controlled amounts of air or oxygen directly into the lungs.

21- Monitoring

- The patient is closely monitored to ensure the tube stays in place and the patient is getting enough air. Vital signs, such as oxygen levels, heart rate, and blood pressure, are regularly checked to ensure the patient's stability
- The patency of the tracheal tube lumen must be assured by regular suctioning. Check routinely to maintain a patent airway.
- If a cuff is present, its pressure and volume should be monitored and adjusted routinely.

- ***Removing the Endotracheal Tube***

22- The tape holding the endotracheal tube on the face is removed, the cuff is deflated, and the tube is pulled out. if the cuff cannot be deflated via the One-way Valve for any reason, then the inflation line should be cut in order to facilitate passive deflation of the cuff.

- Warnings:

❖ ***Do not use*** if package is open or damaged.

- Devices used inflation of the cuff must be clean and free from all foreign matter. The inflation device must be removed from the inflation valve immediately after use
- After inflation of the tracheal cuff, disconnect the syringe from valve. Leaving the syringe attached will keep the valve open, permitting air to come out. The inflation condition of the tracheal cuff should be monitored at all times.
- Due to gas diffusion through the cuff, the internal cuff pressure (or inflation volume) changes over time. If inflation or deflation of the cuff is required, be sure to first evacuate the air completely from the cuff (until pilot balloon is also collapsed) first and then inflate the cuff again to the appropriate volume.
- **Don't Over-inflate the cuff**. Over-inflation can result in tracheal damage, rupture of the cuff with subsequent deflation, or distortion of the cuffs leading to herniation which may lead to airway blockage.
- Deflate the cuff prior to repositioning the tube. Movement of the tube with the cuff inflated could result in patient injury or in damage to the cuff, requiring a tube change. verify the position of tube after each repositioning
- When a patient's position or the tube placement is altered after intubation, it is essential to verify that the tube's position remains correct. Any tube displacement should be corrected immediately as a displaced airway could result in a loss of ventilation.
- **DON'T Reuse** it should discard after single use, Reusing can be associated with Cross infection, Device Malfunction and Reactions to endotoxins as sterilization will not inactivate toxins produced by the breakdown of Gram-negative bacteria even if the bacteria themselves are killed.
- Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability. Contamination and / or limited functionality of the device may lead to injury, illness of the patient.
- **DO NOT re-sterilize and /or reuse the device**, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
- The product **should be used only by a qualified doctor or paramedic** who are experienced and have a thorough understanding of the clinical and technical aspects of product.
- Storage temperature up to 30°C ± 2°C, avoid excessive heat, protect from direct sunlight and moisture.
- For Short Term use.
- The device should be disposed as per the safe disposal instructions as described in the instructions for use.
- Ultramed will not assume any responsibility in case of any incidental or consequential damages resulting from reuse of the product.

- Precautions:

- Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions.
- Failure to do so may result in complications. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged.
- The device is for Single Use Only.
- Do not use if package is open or damaged.

- Check the integrity and functionality of the Endotracheal Tube before use.
- Use the product immediately after opening the individual packing.
- Clinicians should choose the appropriate sizes of the Endotracheal tube according to the patient's age, gender and other specific conditions.
- Proper Sizing, Intubation and Extubation should be in accordance with accepted medical techniques and Expert clinical judgement.
- The user should be alert for anatomical variations including the length of the airway.
- A spare Endotracheal Tube of the correct size should be kept readily available.
- The main lumen of the tracheal tube should be checked for patency prior intubation.
- Before intubation or extubation evacuate air completely from the cuff (until pilot balloon is also collapsed). Otherwise, it may damage the cuff or may be traumatic to the patient's trachea.
- If the tracheal tube is lubricated prior to intubation, it is essential to verify that lubricant doesn't enter and occlude the tube lumen, thereby preventing ventilation.
- Care must be taken to avoid occlusion at the tip part of Endotracheal Tube when applying lubricant.
- Do not apply the petroleum base lubricants it may result in damage to the cuffs, or may be traumatic to the patient's trachea.
- Lubricate with water soluble lubricant as required.
- The use of Lidocaine Topical Aerosol has been associated with the formation of pinholes in PVC cuffs. Instead of that, we recommend to apply lidocaine jelly on tube cuffs
- Each Tube's Cuff, Pilot balloon and valve should be tested by inflation prior to use, if dysfunction is detected in any part of inflation system. The tube should not be used and be returned.
- A Stylet should be readily available and may be used at the clinician's discretion in cases of difficult intubation.
- When using a stylet, verify that it does not protrude from the patient end or Murphy eye.
- Seat the 15mm connector firmly in the adapter on the ventilator equipment to prevent disconnection during use.
- The security of all breathing system connectors should be checked when the breathing circuit is established and frequently thereafter
- Care should be taken to avoid damaging the Thin-walled cuffs by avoiding contact with sharp edges during intubation which would create the need to subject the patient to the trauma of extubation and re-intubation. If cuff is damaged, the tube should not be used.
- The tracheal tube cuff should be slowly inflated with the minimum amount of air required to provide an effective tracheal seal. Intracuff pressure should be closely monitored with a pressure measuring device. As the Pilot balloon is only intended to indicate the presence of pressure in the cuff and is not intended to provide an indication of pressure level.
- Uncuffed ET tube: not ideal when high airway pressures or precise ventilation are required
- Do not gauge the adequacy of cuff inflation on the basis of the volume of air introduced, or the level of resistance felt during inflation.
- Cuff pressure and volume should be monitored and adjusted routinely.
- Breath Sounds Should be monitored to verify correct placement of the tracheal tube and proper ventilation.
- Following intubation, the tracheal tube should be properly secured to help eliminate undesirable movement.

- ❖ A bite block should be used in cases where the patient may bite down and flatten the tracheal tube resulting in blockage.
- ❖ If the Endotracheal Tube needs to be shortened remove the 15mm connector, cut the tube to the desired length **above the designated cut line [The joint between the inflation line and the main body of the tracheal tube]** then replace the 15mm connector with a push and twist action until secure. **Note:** This cannot be carried out on the Reinforced Tubes. **Ensure the suction catheter or any other device is fully removed** from the tracheal tube before cutting. Failure to do so may cause **damage to the catheter, retention of fragments, airway obstruction, or patient injury**.
- ❖ Do not use lubricants to assist the insertion of the 15mm connector into the tracheal tube as disconnection may occur.
- ❖ In the event of change in performance of device observed and same is reflected in ventilator circuit the tube should be replaced.
- ❖ Patients should be adequately humidified to minimize encrustation of the tracheal tube lumen and prevent tracheal mucosal damage. Although generally recommended in intubated patients, the use, method, and intensity of humidification should be guided by the patient's clinical condition and the clinician's judgement
- ❖ The patency of the tracheal tube lumen must be assured by regular suctioning. Check routinely to maintain a patent airway.
- ❖ In the event that unusual positioning of the head or neck is to be required following intubation, use of a reinforced tube should be considered to avoid the potential for kinking.
- ❖ Good clinical judgment should be used when selecting suction catheters, which are intended to be inserted through the endotracheal tube. The current American Association for Respiratory Care clinical practice guidelines recommend choosing suction catheter size based on the external diameter of the suction catheter and the internal diameter of the endo-tracheal tube: a ratio of less than 50% is recommended, to prevent suctioning-related complications.
- ❖ Discard the set after single use.
- ❖ This device does not contain phthalates (DEHP FREE); as marked.
- ❖ Determine patient's condition and vitals status During device application / Operation.
- ❖ Conduct procedure under strict surgical protocol and ensure complete asepsis.
- ❖ Destroy the device after single use as bio-medical waste as per applicable laws.
- ❖ Do not Re-sterilize. Do not Re-use. Single use only.
- ❖ Do not use the device after the Expiry Date.

Potential Complications / Risks:

While intubation can be life-saving, it may come with some side effects. here are some potential side effects of using an **intubation tube:**

- **Trauma:**
  Mechanical or physiological trauma may occur to the naso-/oropharynx, larynx, trachea, or surrounding structures, including abrasions, oedema, inflammation, sore throat, bleeding or haematoma, dental injury, vocal cord or arytenoid injury, neuropathy, salivary gland swelling, epiglottic injury, cervical spine or spinal cord injury, tracheal damage (e.g. ulceration, necrosis, fibrosis, stenosis, perforation), fistula formation, and local or systemic infection.
- **Inadequate oxygenation and/or ventilation:**
  Hypoxia or hypercarbia may result from air leakage due to an inadequate seal, tube

obstruction or kinking, accumulation of secretions or foreign material, malposition (including endobronchial or oesophageal intubation), increased intrathoracic pressure, bronchospasm or laryngospasm, rebreathing, or barotrauma (e.g. pneumothorax, emphysema).

- **Aspiration and regurgitation:**
  Aspiration of gastric contents or debris may occur due to inadequate cuff sealing, gastric insufflation, secondary to oesophageal intubation, or impaired evacuation of gastric contents.
- **Environmental and occupational exposure:**
  Leakage of anaesthetic gases or vapours may occur, posing potential occupational or environmental risks.
- **Device-related hazards:**
  Complications may arise from loss of tracheal seal, loss of tube patency, cuff over- or under-inflation, component failure (e.g. shaft, cuff, connector, inflation line or valve), reuse beyond validated limits, incorrect tube sizing, Incorrect marking and cuff position, or changes in tube position due to patient movement or head and neck repositioning.

General Instructions:
To be used by an expert qualified medical professional. Use maximal sterile barrier precautions during administration. Dispose the device after use as bio-medical waste as per applicable laws.

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartons on each other.
- Nice Ventilated place.
- Out of Sunlight.
- Storage at room temperature up to 30℃ ± 2℃.
- Humidity up to RH 65% (± 5)

Safe Disposal of single-use medical devices:

- adopt adequate precautions for the elimination and disposal of the device and comply with the provisions of the laws in force on biologically hazardous waste.
- Single-use devices must be segregated from other reusable devices and, should not be returned to a Decontamination facility for reprocessing. Once discarded (used or unused) medical devices are considered to be special waste and should be managed as healthcare (clinical) waste. All medical devices that are to be disposed of, must in accordance with Health and Safety, Carriage of Dangerous Goods and Waste Regulations.
- Discarded devices should be placed in UN-type approved waste containers suitable for clinical waste (UN 3291); these should be rigid and puncture-proof. In general devices other than sharps should not be placed in sharps boxes as sharps waste is treated and disposed of in a different manner. Guidance on the type and color of the container should be sought from the Board Waste Management Officer. rigid water-tight containers are used for waste requiring incineration in a suitably permitted or licensed facility.

Method of sterilization

- Sterilized Using Ethylene Oxide

Shelf life

- 5 years (from the date of manufacturing)

Basic UDI:

ULTRAMED ENDOTRACHEAL TUBE ORAL/NASAL Cuffed & Uncuffed	622300425ETT4005WV
ENDOTRACHEAL TUBE Preformed Oral	622300425ETT4010/PON7
ENDOTRACHEAL TUBE Preformed Nasal	622300425ETT4010/PNN5

Reporting of incident to Manufacturer & Competent Authority:

- For providing feedback on this product write to shady@ultramedumic.com
- In case of any serious incident occurred, please report it to the Ultra for medical products (ultramed) Co (U.M.I.C) S.A.E and/or its Authorized Representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Details of symbols used in labels:

Symbol	Meaning
EU REP Obelis SA 53 Bd. Général Wahis B-1030 Brussels,Belgium Phone : 32.2.732.59.54 Fax : 32.2..732.60.03 E-mail: mail@obelis.net www.obelis.net	EU REP
CE 2803	CE Mark with notified body number 2803
STERILE EO	Sterilized by Ethylene Oxide
	For Single Use Only
LOT	Lot No.
	Date of Manufacturing
	Use by / Expiry date
REF	Catalogue No.
	Non- Pyrogenic
MD	Medical Device
UDI	Unique device Identifier
	Don't use if package is not intact
	Manufacturer's address
PHT NON-DEHP	Phthalate-Free
	Read Instructions for Use

Symbol	Meaning
	Not to be re-sterilized
	storage at room temperature up to 30 ℃ ± 2℃
	MR Unsafe [For Cuffed and Reinforced Endotracheal Tube]
	MR Safe [For Uncuffed Endotracheal Tube]
	Cautions
	Latex Free
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“
	Recycle
	Don’t put more than 5 cartons upon each other

ISSUE/REV DATE: 01 -09- 2013 / 01.05.2024

Assiut Factory: Part no. (304:310) and part no. 312 - Arab El Awamer - Industrial zone – Abnoub - Assiut, Egypt.
Tel: 088/4960500 – 4960600 & **Fax:** 088/4960400 & **Mob:** 0101558853
Cairo Head Office: 64, Nakhla El Motaiy Triumph Square Heliopolis **Tel:** 022/4171621-4143794 & **Fax:** 022/4171613 & **Mob.** 0123988200
Assuit Office: 23, July Str. **Tel:** 088/2364111 – 2364222 & **Fax:** 088/2334964 & **Mob. :** 0123988202
Alexandria Office: 212Abd El salaam Airef Str, Luran **Tel:** 03/5856202– 5856458 & **Fax:** 03/5828988& **Mob:** 0123948666
E-mail: info@ultramedumic.com , shady@elaggargroup.com **Website:** www.ultramedumic.com