# IFU

# Tracheostomy Tube

## DESCRIPTION

The Tracheostomy Tube is supplied sterile with a 15mm connector. The tube is inserted into the patients trachea via a small surgical opening in the throat. The Tracheostomy is performed for short term or long term ventilation, patients in Intensive Care Units who require long term ventilation are ventilated via the Tracheostomy tube.

## MODEL AND SIZE

| Category | Model Code | Model description | Size(ID) |
|---|---|---|---|
| Standard Tracheostomy Tube | TT-P1 | Standard, Uncuffed | 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0 |
| | TT-P2 | Standard with cuff | |
| | TT-P3 | Standard with AccuCuff™ | |
| | TT-P4 | Standard with cuff(PU) | |
| | TT-P5 | Standard with AccuCuff™(PU) | |
| Tracheostomy Tube Reinforced | TT-J1 | Tracheostomy tube Reinforced(Uncuffed) | 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0 |
| | TT-J2 | Reinforced with cuff | |
| | TT-J3 | Reinforced with AccuCuff™ | |
| | TT-J4 | Reinforced with cuff(PU) | |
| | TT-J5 | Reinforced with AccuCuff™(PU) | |
| Tracheostomy Tube with subglottic suction port | TT-X2 | Tracheostomy tube with subglottic suction port | 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0 |
| | TT-X3 | Tracheostomy tube with subglottic suction port and AccuCuff™ | |
| | TT-X4 | Tracheostomy tube with subglottic suction port (PU) | |
| | TT-X5 | Tracheostomy tube with subglottic suction port and AccuCuff™(PU) | |
| Extra-Length Tracheostomy Tube with subglottic | TT-XC2 | Extra-Length tracheostomy tube with subglottic suction port | 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0 |
| | TT-XC3 | Extra-Length tracheostomy tube with subglottic suction port and AccuCuff™ | |

| | | | |
|---|---|---|---|
| suction port | TT-XC4 | Extra-Length tracheostomy tube with subglottic suction port (PU) | |
| | TT-XC5 | Extra-Length tracheostomy tube with subglottic suction port and AccuCuff™(PU) | |
| V Cuff | TT-VP8 | Standard with cuff(PU) (V Cuff) | 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0 |
| | TT-VJ8 | Reinforced with cuff(PU)(V Cuff) | |
| | TT-VX8 | Tracheostomy tube with subglottic suction port (PU) (V Cuff) | 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0 |
| | TT-VXC8 | Extra-Length tracheostomy tube with subglottic suction port (PU) (V Cuff) | |

## INTENDED USE

It is used to establish artificial airway after performing emergency tracheostomy.

## PATIENT GROUPS

Children, adults.

## INTENDED USERS

Professionally trained doctors or clinical nurses.

## INDICATIONS

a) Laryngeal obstruction

Patients with acute laryngitis, edema of the larynx, laryngeal and hypopharyngeal tumors, diphtheria, abduction paralysis of vocal cord, cicatricial stenosis of larynx and trachea, and dyspnea caused by compression of adjacent organs or larynx and organs.

b) Retention of secretions in the lower respiratory tract

Retention of secretions in the lower respiratory tract caused by coma (craniocerebral trauma, barbiturates and other drug poisoning), Guillain-Barre syndrome, tetanus, poliomyelitis and other neurological and muscular disorders; Obstruction of lower respiratory secretions after thoracic trauma, spinal trauma (paralysis), or various surgeries in order to suck sputum and keep airway unobstructed, tracheostomy can be considered.

c) Preventive tracheostomy

For some patients who had head and neck surgery, oral and maxillofacial surgery and pharyngeal surgery, tracheostomy can be performed preoperatively or after surgery when the airway is block due to the postoperative defects, tissue swelling, hemorrhage and other factors caused by nerve, muscle, jaw function and surgical trauma.

d) Removal for the foreign bodies in respiratory tract

If the foreign bodies in respiratory tract failed to be removed by forceps under endoscope, it is estimated that there is a risk of asphyxiation when retaken, or there is no equipment and technology for tracheoscopy, the trachea foreign body can be removed by tracheostomy.

e) Respiratory insufficiency or respiratory failure

Respiratory insufficiency or respiratory failure due to various reasons. Such as trauma or anesthesia surgery caused by respiratory dysfunction or respiratory failure, pulmonary edema, pneumothorax, hemopneumothorax, etc. Chronic lung diseases (chronic bronchitis, chronic emphysema, COPD); Pulmonary heart disease, pulmonary cardio-encephalopathy, etc.; Respiratory failure caused by shock, hypersensitivity, poisoning, etc., such as acute respiratory distress syndrome, requiring mechanical ventilation and suction of secretions and blood sputum of the lower respiratory tract.

## CONTRAINDICATIONS

a) Acute surgical tracheal management
b) It is forbidden to use percutaneous dilatational tracheostomy for children
c) Unable to mark the physiological anatomical position with certainty
d) Local lesion in neck
e) Coagulation dysfunction
f) Obese patients with short and thick necks

## COMBINATIONS

Devices used in surgery: disposable interventional surgery kit (open operation), scalpel, stylet (assist product insertion when intubation is difficult), syringe (inflate the cuff), anesthesia machine (anesthesia gas was introduced through tracheotomy intubation for surgical anesthesia).

Devices used during ventilating: ventilator (to provide oxygen to the patient while monitoring various

parameters during breathing), disposable suction tube (to suck sputum to prevent obstruction of tracheostomy tube).

## WARNING/PRECAUTIONS

1) Sterile product. Sterilized by Ethylene Oxide.
2) Single use only. Do not re-sterilize or reuse which will cause cross infection.
3) It is strictly prohibited to use if the package is damage, leakage, exceeds the expiry date or containing foreign matter.
4) After use, the product should be completely scrapped. And the products should be completely scrapped, and put into the disposable product waste designated by the hospital, which will be treated by the hospital in accordance with local laws and regulations.
5) If use cuffed products, please try to fill the cuff prior to use and observe whether there is leakage. If there is air leakage, it is strictly prohibited to use.
6) Tracheostomy Tube (standard/reinforced) is suitable for adult and children, clinicians should select appropriate size according to the patient's age, gender and other specific conditions. Products with cuff pressure indicator are only suitable for adults.
7) Tracheostomy Tube with subglottic suction port and Extra-Length Tracheostomy Tube with subglottic suction port are suitable for adults, and clinicians should select appropriate sizes of Tracheostomy Tube according to the patient's age, gender and other specific conditions.
8) Before using Tracheostomy Tube with subglottic suction port or Extra-Length Tracheostomy Tube with subglottic suction port), the suction tube should be tested to ensure the suction tube is unobstructed.
9) In case of allergic reaction, please contact the doctor in time.
10) The duration of body contact of Tracheostomy Tube should be less than 7 days. For cuffed products, the cuff pressure should be checked per hour.
11) This product should only be used by professionally trained doctors and clinical nurses. Read the instructions carefully before use.
12) It is used by respiratory, anesthesiology, emergency and intensive care unit (ICU) physicians in the medical sector to establish artificial airway.

13) Do not use the Reinforced Tracheostomy Tubes during MRI scan. (Note: Tracheostomy tubes with reinforced spring can produce displacement, artifact,heat generation, and magnetic torsion forces under MRI, which can be life-threatening in severe cases).
14) Syringes, 3-way stopcocks or other lure tip devices should not be left inserted in the cuff pressure indicator or check valve for a long time for the leakage of cuff.
15) Do not use a laser near the tracheostomy tubes as this may cause combustion and injury. (Note: Contact of the beam or electrode with the tracheostomy tube, especially in the presence of oxygen-enriched or nitrous oxide containing mixtures could result in the rapid combustion of the tube with harmful thermal effects and with emission of corrosive and toxic combustion products including hydrochloric acid (HCI).)

## PRE-USE CHECKS:

1. Do not use this product unless these checks are fully satisfactory.
2. Device is supplied sterile if packaging is unopened, undamaged and within shelf-life date.
3. Visually check whole device for completeness, discolouration, damage and flaws.
4. Test inflate cuff (if applicable)prior to use – do not over inflate
   - Check against leaks and herniation of the cuff and leaks from the inflation valve.
   - Check that the airway tube is clear with no blockage or occlusion
5. In the unlikely event of pre-use check failure, do not use but return to supplier for inspection.

## DIRECTION FOR USE

These directions are general guidelines intended for use by qualified medical personnel. Any instructions, indications and contraindications given are not exhaustive and it is the clinician's responsibility to ensure the safe, correct use of this product.

a. It should be operated and used by the doctor or clinical nurse who has been trained professionally.
b. Disposable medical gloves should be worn during insertion, and the gloves should be discarded after insertion to prevent cross-infection.
c. Choose the appropriate size of tube. Before use, a doctor or nurse should check the packaging for any damage. Then open the package, take out the tube, and inject gas into the cuff (if any) with a syringe to observe whether there is any leakage. If there is no air leakage, deflate the cuff (if any) until the cuff is flat and close to the wall of the tube.

d. Insert the tube into the patient using correct medical technique (the user should avoid the cuff being broken by foreign bodies, and the broken cuff may result in tube dislocation and VAP).

e. After insertion in place, firm the tube with a fixed belt to prevent it from falling off or shaking freely.

f. Inflate the cuff with a syringe and observe the pilot balloon to prevent excessive intracuff pressure. Inflate the cuff with a syringe and observe the cuff pressure indicator (if any) if the black line is located in the green area , that is as the safe pressure.(For V Cuff series, deflate before insertion and there is no need to inflate)

g. Note: When using the syringe to inject air into the cuff pressure indicator, you need to turn the syringe forward and rotate 90° to the right.

h. Withdraw the introducer and connect the tracheostomy tube connector with the respiratory equipment.

i. Use the chest X-ray to observe the exact position of intubation

j. Before extubation, completely deflate the cuff, so the black line of cuff pressure indicator is located near the white line (if any). (This Article is suitable for Standard Tracheostomy Tube and Tracheostomy Tube Reinforced)

k. Before extubation, the secretions above the cuff should be cleaned through the suction connector, and then the gas in the cuff should be completely released, that is, the black line of the cuff pressure indicator is located near the white line (if any). (This Article is suitable for Tracheostomy Tube with subglottic suction port and Extra-Length Tracheostomy Tube with subglottic suction port)

## SHELF LIFE

5 years

## Duration

Less than 7 days

## STORAGE CONDITIONS

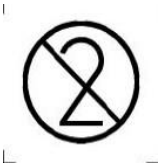
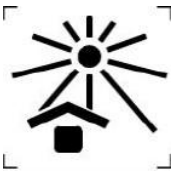
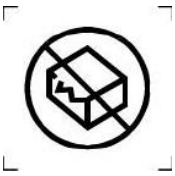
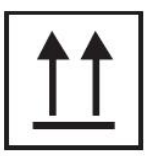
Store product inside containers or outer boxes in a clean, dry area.

Storage should be within a temperature range of 10–30$^{0}$ C.

Do not expose to direct sunlight or UV light.

**Made in China**

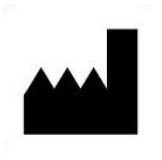
# MEANING OF SYMBOLS ON PACKAGE

| | | | |
|---|---|---|---|
|  | Do not re-use |  | Manufacturer |
|  | Use-by date |  | Date of manufacture |
|   | Batch code |   | Authorized representative in the European Community |
|   | Sterilized using ethylene oxide |  | Keep away from sunlight |
|  | Do not use if package is damaged |  | Keep dry |
|   | Consult instructions for use |   | Catalogue number |
|  | Caution |   | Doesn't contain DEHP |
|   | CE marking of conformity |   | Latex free |
|  | This way up |  | Fragile,Handle with care |


MR Safe


MR unsafe


MR Conditional



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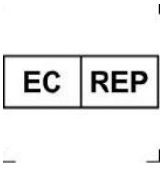


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