CE 2862

[Product Name]
Tracheostomy Tube

[Intended Use]
Tracheostomy Tube is used for clinical emergency tracheostomy to establish artificial airway.

[Type and Specification]
See attachment 1

[Indication]
1) Upper respiratory tract obstruction.
2) Severely ill patients who need to receive mechanical ventilation for a long time.
3) Difficulty in expectoration, resulting in retention of secretions in the lower respiratory tract.
4) Extreme dyspnea, unconditional tracheal intubation.

[Contraindications]
There is no contraindication for this product currently, but the following should be taken into account:
1) Cause and tracheostomy purpose.
2) Degree of obstructive dyspnea.
3) Patient condition and hospital condition.

[Use Method]
- **Pre-operative preparation**

1) Routine pre-operative examination.
2) For patients with severe dyspnea, continuous inhalation of high flow oxygen can be given.
3) Necessary symptomatic treatment: Patients with high temperature should be given cooling treatment; those who are restless should be given sedative treatment; those who are injured outside the larynx should be given a certain dose of hemostatic drugs first.
4) Prepare the device for intubation.
5) Anesthesia before intubation.
6) Confirm the specification of the tube.
7) Preparation of patient's position.

The patient should be placed into the supine position on the operating table and, if possible, a small pillow should be placed horizontally under the patient's shoulder to keep the neck in hyperextension.

- **Insert the tracheostomy tube**

1) After performing tracheostomy in accordance with the procedure, the tracheal incision shall be quickly opened with a retractor or curved hemostatic forceps and properly expanded; if secretions cough out of the tracheal incision, they can be sucked out with an aspirator and then an appropriate tracheostomy tube can be inserted into the expanded tracheal incision.
2) After the intubation is in place, the introducer can be removed; if there are secretions in the lumen, they can be sucked out by the suction catheter.
3) Inflate the cuff. When the trachea and the cuff are satisfactorily closed, the anesthesiologist shall examine the pulmonary ventilation.

- **Fix the tracheostomy tube**

Place the tape on the neck-plate at the machine end of the tube around the patient's neck and tie a knot in the middle on the back of neck to a degree of tightness that is just enough to insert a finger. If the skin incision is longer, 1 or 2 stitches can be sutured above the incision, and the wound below the tube can be sutured to avoid subcutaneous emphysema and facilitate wound drainage. The wound can be covered with an open gauze placed around the tube. The machine end of the tube is connected to HME or covered with 1 or 2 layers of aseptic wet gauze or connected to a ventilator.

- **Postoperative care**

1) The postoperative ward is required to be a rescue ward or an intensive care unit, and the ward should be quiet with a certain temperature and relative humidity. Sprinkle more water on the floor when the indoor air is dry to ensure sufficient water vapor. Keep the air circulating and fresh.
2) The patients should be cared for by special personnel.
3) The necessary rescue equipment and drugs should be prepared after operation.
4) After operation, the patient should be in the horizontal recumbent position, or in semireclining position, making the neck stretch to facilitate unobstructed respiratory tract and cough. Because the patient has a loss of ability to suck after operation, the type and timing of diet should follow the doctor's instructions.
5) The changes of the condition of primary disease, especially the changes of respiratory function, should be closely observed after the operation in order to prevent complications.
6) Pay attention to keeping the lower respiratory tract unobstructed.
7) Two to three days after operation, patients may be advised to get out of bed to prevent complications such as pulmonary infection. However, whether in bed rest or walking, the head should be in a straight position and should not be turned suddenly and violently. Do not excessively lean back and bend your head forward.
8) The management of intubation, the monitoring and treatment of important organ function and the treatment of early and late complications after operation were carried out in accordance with hospital regulations.
9) Double-cuff, which is replaced every 1 hour to 3 hours after the operation, and every 4 hours after 72 hours or as necessary; when the patient is awake, communicate with the patient first. Inner Cannula: The recommended service time is 10 days when the inner tube is not used; while the recommended service time is 1 month when the inner tube is used. Within 24 to 48 hours after operation, it should be replaced every 1 to 4 hours, and then every 12 hours or as necessary; when the patient is awake, communicate with the patient first. Before pulling out the inner tube, suck sputum first. Pull out the inner tube carefully to prevent the patient from coughing.
10) The cleaning method of the inner tube is to soak in saline for 15 minutes; use a cleaning brush to clean up the attachments on the tube wall; after flushing the inner tube with saline, let it dry naturally.

[Warnings and Precautions]
1) This product is suitable for patients who need anesthesia, artificial ventilation or other assisted breathing.
2) This product is sterilized by ethylene oxide with validity for 2 years. If it has expired, it is forbidden to use.
3) Before use, please check the package. Do not use if the package is damaged. According to the relevant regulations of the hospital or local health and family planning authorities, harmless disposal should be done by a qualified or authorized institution.
4) Once the aseptic package is opened, even if the product is not used, it must be destroyed. According to the relevant regulations of the hospital or local health and family planning authorities, the destruction shall be handled harmlessly by a qualified or authorized institution.
5) It is for one-time use. After use, the harmless disposal should be done by a qualified or authorized institution according to the relevant regulations of the hospital or local health and family planning authorities.
6) Avoid contact with the laser bean or electrosurgical electrode, which can ignite a mixture of carbon monoxide and oxygen or pure oxygen in the tube.
7) The cuff should not be in contact with sharp objects such as forceps, because this may damage the cuff. If there is any damage, it is forbidden to use.
8) Check whether the cuff leaks before use. Pay attention to the air volume during the inflation test and during the inflation in the operation, so as to avoid the damage of cuff due to excessive inflation.
9) Before intubation in the tracheotomy, the cuff and the tip of tube should be lubricated sufficiently. Otherwise, the cuff may be damaged or the respiratory tract of the patient may be hurt.
10) During intubation, we should focus on monitoring the patient's blood pressure, heart rate, respiratory rate, electrocardiogram, and

$Sp0_2$, especially in patients undergoing emergency tracheostomy, to timely identify changes in patient's condition.

11) Hyperextension of the neck should be contraindicated in patients with suspected or confirmed cervical spine injury.
12) The air volume of cuff should be determined by doctors according to clinical judgment. Overinflation may damage the cuff or cause damage to the patient's respiratory tract.
13) The air volume of cuff should be monitored at any time. Because air diffusion is through the cuff, the pressure (or expansion) of the cuff will gradually change. If the cuff needs to be inflated or deflated, it is necessary to empty the air in the cuff (indicating that the balloon is completely flat), and then inflate the cuff to the appropriate volume.
14) The tracheostomy tube shall not be used in any case of air leakage or protrusion of the cuff.
15) Do not pull the inflating tube excessively during use, otherwise it may lead to air leakage or damage of the tube.
16) Before intubation/extubation, adjust the position of the cuff and ensure that the air in the cuff is completely discharged (the indicator balloon is completely flat), or otherwise the cuff may be damaged or the respiratory tract of the patient may be hurt.
17) Do not cut the length of the tube or open holes in the tube body by yourself.
18) The tracheostomy tube should be used by professional doctors in operating rooms of professional medical institutions and in fully disinfected environments, with the participation of anesthesiologists, so as to monitor patients, control the respiratory tract by tracheal intubation before tracheostomy, and make adequate preparation for intubation and necessary first aid measures before intubation.
19) During the use of tracheostomy tube, routine examinations should be carried out on a daily basis. If air leakage, displacement or accidental detachment of the tracheostomy tube is found, the doctor should be notified immediately, who shall assess the patient's condition, closely observe the changes of vital signs and blood oxygen saturation of the patient, and then handle the patient's condition according to the emergency plan formulated by the hospital.
20) The tracheostomy tube can be used in combination with devices such as the heat and moisture exchanger (hereinafter referred to as HME) and disposable breathing circuit (hereinafter referred to breathing circuit). The connection end of HME, breathing circuit and tracheostomy tube should be the 15 mm female conical connector in accordance with EN ISO 5356-1:2015. Then the patient's condition should be handled according to the emergency plan formulated by the hospital.

After the tracheostomy tube is implanted in place, the breathing circuit adapter is connected to the tracheostomy tube connector. If it is necessary to cooperate with the HME, the patient end of the HME is connected to the tracheostomy tube connector, the machine end is connected to the breathing circuit adapter, and the machine end of the breathing circuit is connected to the ventilator or anesthesia machine for ventilation. It should be noted that the connector connection must be firm and tight, otherwise it may cause accidental detachment or air leakage.

21) Please strictly observe the corresponding surgical procedures and prohibit illegal operations.
22) Nursing after operation should be done well to avoid complications as far as possible. Extubation must be carried out under the condition that the patient can breathe spontaneously and is awake, and equipped with necessary first aid measures. After extubation, the vital signs of the patient should be closely observed, and good nursing should be done, especially paying attention to maintaining airway patency.
23) The recommended indwelling time for the tracheostomy tube should not exceed 7 days. The recommended indwelling time for tracheostomy tube with inner cannula should not exceed 30 days.
24) The inner tube can be immersed in saline for 15 minutes each time at most 20 times.
25) Please inform the manufacturer and competent authority in case of any adverse event related to the device.

[Shelf-life]
Five years

[Sterilization Method]
Ethylene oxide

[Transport and Storage]
1) No heavy pressure, direct sunlight, rain or snow dipping, so as not to damage the device.
2) Handle with care during transport and avoid violent collision.
3) The device should be far away from fire and heat source to prevent it from being deformed due to heat;
4) Store in a cool and dry place, and ensure that the room is well ventilated with no corrosive gas, and the relative humidity does not exceed 80%.

[Production Date]
See on the package.

[Symbol Explanation]

	Manufacturer		Date of manufacture
EC REP	Authorized representative in the European Community/ European Union	LOT	Batch code
	Use-by date		Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use		Caution
	Do not resterilize, Indicates a medical device that is not to be resterilized-		Do not re-use
STERILE	Sterile	STERILE EO	Sterilized using ethylene oxide
MD	Medical device	UDI	Unique device identifier
CE 2862	CE Marking	REF	Catalogue number
	Keep away from sunlight		Keep dry
	Fragile, handle with care		Stacking layer limit
	Up		

[Manufacturer]
Henan Tuoren Medical Device Co., Ltd.
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E-mail: info@etuoren.com
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EC REP **[EU Representative]**
MedNet EC-REP GmbH
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E-mail: contact@mednet-ecrep.com

Attachment 1

REF	Type	Specification	Componmennts
TYN0025	Normal Cuffed	2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm	It is comprised of the neck-plate, fixed belt, introducer, tube body, cuff, inflating tube, indicator balloon and one-way valve.
TYN0030			
TYN0035			
TYN0040			
TYN0045			
TYN0050			
TYN0055			
TYN0060			
TYN0065			
TYN0070			
TYN0075			
TYN0080			
TYN0085			
TYN0090			
TYN0095			
TYN0100			
TYN1025	Normal Uncuffed	2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm	It is comprised of the neck-plate, fixed belt, introducer, tube body.
TYN1030			
TYN1035			
TYN1040			
TYN1045			
TYN1050			
TYN1055			
TYN1060			
TYN1065			
TYN1070			
TYN1075			
TYN1080			
TYN1085			
TYN1090			
TYN1095			
TYN1100			
TYR0025	Reinforced Cuffed	2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm	It is comprised of the neck-plate, fixed belt, introducer, tube body, spring, cuff, inflating tube, indicator balloon and one-way valve.
TYR0030			
TYR0035			
TYR0040			
TYR0045			
TYR0050			
TYR0055			
TYR0060			
TYR0065			
TYR0070			
TYR0075			
TYR0080			
TYR0085			
TYR0090			
TYR0095			
TYR0100			

TYR1025	Reinforced Uncuffed	2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm	It is comprised of the neck-plate, fixed belt, introducer, tube body, spring.
TYR1030			
TYR1035			
TYR1040			
TYR1045			
TYR1050			
TYR1055			
TYR1060			
TYR1065			
TYR1070			
TYR1075			
TYR1080			
TYR1085			
TYR1090			
TYR1095			
TYR1100			
TYD0070	Double-cuff	7.0mm, 7.5mm, 8.0mm	It is comprised of the neck-plate, fixed belt, introducer, tube body, upper cuff, under cuff, inflating tube, indicator balloon and one-way valve.
TYD0075			
TYD0080			
PDTY0070	Percutaneous Dilation Cuffed	7.0mm, 7.5mm, 8.0mm	It is comprised of the neck-plate, fixed belt, introducer, tube body, cuff, inflating tube, indicator balloon and one-way valve.
PDTY0075			
PDTY0080			
PDTY1070	Percutaneous Dilation Uncuffed	7.0mm, 7.5mm, 8.0mm	It is comprised of the neck-plate, fixed belt, introducer, tube body.
PDTY1075			
PDTY1080			
STY0060	Suction	6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm	It is comprised of the neck-plate, fixed belt, introducer, tube body, suction catheter, suction connector, protective cap, cuff, inflating tube, indicator balloon and one-way valve.
STY0065			
STY0070			
STY0075			
STY0080			
STY0085			
ITN0050	Inner Cannula Normal	5.0mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm	It is comprised of the stopper, one-way valve, indicator balloon, inflating tube, introducer, neck-plate, machine end connector, protective cap, inner tube, outer tube, cuff, fixed belt, spunlaced with holes.
ITN0060			
ITN0065			
ITN0070			
ITN0075			
ITN0080			
ITS0050	Inner Cannula Suction	5.0mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm	It is comprised of the stopper, one-way valve, indicator balloon, inflating tube, introducer, neck-plate, machine end connector, inner tube, outer tube, cuff, fixed belt, suction catheter, suction connector, protective cap, spunlaced with holes.
ITS0060			
ITS0065			
ITS0070			
ITS0075			
ITS0080			
ITF0050	Inner Cannula Fenestrated	5.0mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm	It is comprised of the stopper, one-way valve, indicator balloon, inflating tube, introducer, neck-plate, machine end connector, protective cap, inner tube, outer tube, cuff, fixed belt, spunlaced with holes.
ITF0060			
ITF0065			
ITF0070			
ITF0075			
ITF0080			