All Silicone Tracheostomy Tube (Uncuffed)

Do not reuse

[WARNINGS]

< Operating and using method >

[1] After tracheostomy, if the route from the skin to the trachea has not been established, pay due attention because it may be difficult to reinsert the tube. For details, see [1] and [2] of **[PRECAUTIONS IN USE] < Important basic precautions >**.

[2] When connecting the product to the respiratory circuit make sure that the tube is connected securely (Securely connect the tube to the respiratory circuit without leakage, occlusion, loosening on the connection, etc.).
[Incomplete connection may cause ventilatory impairment, etc.]
For details, see [6] of **[PRECAUTIONS IN USE] < Important basic precautions >**.

[3] If high concentration oxygen is administered via the product, as a general rule, do not use a laser surgical scalpel or an electrical scalpel in the vicinity of the product.
[Sudden inflammation in oxygen, possible inhalation injury and generation of toxic gas may occur due to inflammation.]

[CONTRAINDICATIONS, PROHIBITIONS]

[1] Do not reuse the product (single use for one case).
[The product is single use only and disposable, and its quality or performance after one use is not guaranteed. Further, reuse carries the possible risk of contamination (infection) to patients. Contamination of the product may lead to patient injury, illness or death.]

[2] Prohibition of reprocessing, re-sterilization.
[Reprocessing of the product may lead to defects. It may also cause patient injury, illness or death.]

< Medical devices to be used in combination >

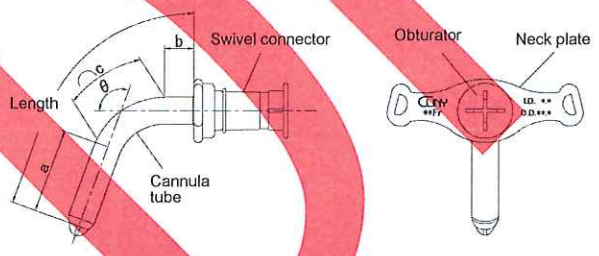
Do not connect the product to a connector of the Norman Elbow type (shape with the inner cylinder for gas supply inside the connector protrudes toward the patient). For details, see **< Interactions (concerning to be used in combination with other drugs or medical devices etc.) >** in **[PRECAUTIONS IN USE]**.

[SHAPE, STRUCTURE, AND PRINCIPLE]

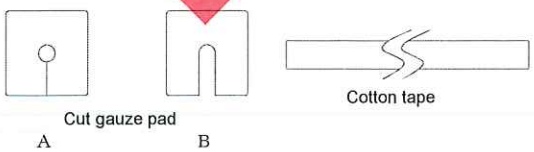
The product is sterilized with ethylene oxide gas.

< Shape >

- Tracheostomy tube (Uncuffed)



- Hygiene set



Size (inner diameter)	Outer diameter (mm)	Length (mm)	a (mm)	b (mm)	c (mm)	θ (°)
5.0	7.3	57.0	26.0	8.0	23.0	110
6.0	8.7	63.0	28.0	10.0	25.0	110
7.0	10.0	71.0	31.0	12.0	28.0	110
7.5	10.7	73.0	32.0	12.0	29.0	110
8.0	11.0	75.0	33.0	12.0	30.0	110
8.5	11.7	78.0	34.0	13.0	31.0	110
9.0	12.3	80.0	35.0	13.0	32.0	110
9.5	13.3	83.0	36.0	14.0	33.0	110

< Raw materials >

- Tracheostomy tube: Silicone rubber and polypropylene
- Hygiene set: Cotton

< Principle >

Fenestrate the trachea to insert the product. Fix and place it to manage the respiratory tract. Connect an appropriate ventilator and anesthetic device to the cannula.

[INTENDED USE]

Used as the tube to be inserted in the trachea for the purpose of managing the respiratory tract etc. during tracheostomy. (except for neonates)

[EFFICACY OR EFFECT]

The respiratory tract can be managed.

[PERFORMANCE]

- Secure the sterility assurance level (SAL) 10^{-6}.
- Sterile residues: Shall conform to ISO10993-7.
- Shall not contain biological substance and conform to biological safety requirements.
- Shall be durable for 29 days continuous use.
- Shall maintain the stability and durability for 5 years.
- The following criteria shall be met:

Swivel connector fixation strength
When a force of 50 ± 5 N is applied at 50 ± 5 mm/min by holding the connector and tube, it shall not move in the axial direction.

Neck plate fixation strength
When a force of 50 ± 5 N is applied at 50 ± 5 mm/min by holding the connector and tube, it shall not move in the axial direction.

[OPERATING AND USING METHOD]

The general operational procedure is described below.

< Placement method >

[1] Prepare necessary apparatuses for tracheostomy and intubation.
Apparatuses to be prepared: Appropriate amount of skin disinfectant, water-soluble lubricant, anesthetic, etc., various apparatuses for tracheostomy, suction device and suction tube, dilation forceps.

[2] Before taking out the product, check whether there is any abnormality in the product and packaging.

[3] Take out the product from the packaging, and check that all components are available.

[4] Properly position the patient for operative procedure.

[5] Disinfect the surgical site with disinfectant.

[6] After local anesthesia with anesthetic, expose the trachea to perform tracheal fenestration by total amputation, flap amputation or circular incision.

[7] Insert the dilatation forceps.

[8] Open the incision site with the dilation forceps, and insert the tracheostomy tube with the obturator attached. After intubation, remove the obturator.

[9] Since the tracheostomy tube is easy to fall out by coughing, etc., hold the tube firmly with fingers, and suction the blood in the tracheostomy tube quickly.

[10] Locate the sites of bleeding (particularly in the edge of the thyroid sectioned) and perform hemostatic technique properly to place 1 or 2 suture(s) in the upper edge and lower edge of the skin incision site.

[11] Apply the cut gauze pad contained in the hygienic set around the tracheostomy tube, and place the cotton tape around the neck to fix the tracheostomy tube. Keep a space where can be inserted one or two fingers between the cotton tape and the neck, if necessary in this case.

[12] Connect appropriate ventilation units such as ventilator and anesthetic device to the swivel connector as necessary.

< Extubation method >

[1] Disconnect the ventilation unit from the swivel connector.

[2] Extubate slowly.

< Replacement method >

[1] Check the product, etc. according to [2] to [3] of the above < **Placement method** >.

[2] Properly position the patient for operative procedure.

[3] Disinfect the tracheostomy stoma as necessary.

[4] Insert the tracheostomy tube with the obturator attached. After intubation, remove the obturator.

[5] Apply the cut gauze pad contained in the hygienic set around the tracheostomy tube, and place the cotton tape around the neck to fix the tracheostomy tube. Keep a space where can be inserted one or two fingers between the cotton tape and the neck, if necessary in this case.

[6] Connect appropriate ventilation units such as ventilator and anesthetic device to the swivel connector as necessary.

< Precautions in use related with the method of use >

[1] Do not occlude the lumen of the tracheostomy tube with lubricant.
[It may be difficult to manage the respiratory tract.]

[2] The product may be caught by granuloma, making it difficult to remove the product or bleeding may occur. Therefore, pull out the product slowly and carefully when removing it.

[3] After removal, observe the patient for symptoms of ventilatory failure such as dyspnea.

[4] To manage the respiratory tract promptly if ventilation failure occurs after removal, prepare for procedures such as tracheal intubation in advance.

[PRECAUTIONS IN USE]

< Important basic precautions >

[1] To prevent the product from being dislodged, fix the product appropriately using the cotton tape provided with the product, etc.
[If fixation is loosened, the cannula may be dislodged from the trachea.]

[2] After tracheostomy, take measures to securely fix the product so that it is not dislodged. In addition, for reinsertion after incision or accidental removal, prepare for emergency tracheal intubation, etc. in cases of subcutaneous placement at a different site or difficulty in insertion.

[3] When using the product in a patient who is difficult to express his/her will such as pediatric patients, patients with impaired consciousness and patients with dementia, observe the patient very carefully since obstruction in the respiratory tract may not be detected promptly.

[4] To minimize coagulation of secretions inside the cannula and humidify the respiratory tract of the patient adequately to prevent damages to the respiratory tract mucosa.

[5] To prevent obstruction due to secretions etc. adhered inside the cannula, perform suction as appropriate.

[6] When connecting a respiratory circuit to the product, avoid applying excessive force to the product.
[It may cause dislodgment of the product from the trachea, disconnection of the respiratory circuit, obstruction of the product or the respiratory circuit.]

[7] The product should be replaced by new one according to the condition of the patient, local deformation or stain on the product etc.

[8] To avoid self-removal, patients should be provided with information that they may not be able to vocalize postoperatively for a while, but it is easy to close the incision site when their respiratory status becomes stable and they will be able to vocalize without fail. If time allows, determine the means of communication in consultation with patients and practice to use it in advance.

[9] Do not obstruct the swivel connector of the product.
[Obstruction of the swivel connector may result in poor ventilation, and the patient may develop dyspnea, cyanosis, etc.]

[10] Before using the product, check whether there is any abnormality in each part.

[11] Do not intubate forcibly. If insertion is difficult, discontinue the use and take appropriate measures.
[Tissues etc. may be damaged.]

[12] Do not intubate or extubate forcibly. Operate the product with great care.
[The product may be damaged.]

[13] If any abnormality is observed, discontinue the use of the product immediately and take appropriate measures.

[14] Do not pull or bend the product forcibly during use. Handle it carefully.

[15] Do not modify the product.
[If a side hole, etc. is added, the tube may be cut.]

[16] Do not grip the product strongly with forceps, etc.

[17] Do not use the product if the packaging is damaged or if any abnormality such as damage is found in the product.

[18] Use immediately after opening and dispose in a safe manner for each country after use.

[19] During placement, keep the product under full control to prevent its handling by an untrained person.

[20]  printed on the label means that the product should not be used if the package is damaged or opened.

[21]  printed on the label means that the product does not contain phthalic acid in the contact part of the body fluid/drug solution.

[22] Any serious incident that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

< Interactions (concerning to be used in combination with other drugs or medical devices etc.) >

1. Contraindications to be used in combination (Do not use in combination)

Name, etc. of medical device	Clinical symptoms and measures	Mechanism and risk factors
Medical devices with a connector of the Norman Elbow type (shape with the inner cylinder for gas supply inside the connector protrudes toward the patient)	Do not connect medical devices with a connector of the Norman Elbow type to the product.	The product may be obstructed, causing hyperinflation of lungs or ventilation failure.

2. Precautions to be used in combination (Precautions when using in combination)

Name, etc. of medical device	Clinical symptoms and measures	Mechanism and risk factors
Laser treatment device Electrosurgical unit	If high concentration oxygen is administered via the product, as a general rule, do not use a laser treatment device (laser surgical scalpel) or an electrosurgical device (electrical scalpel) in the vicinity of the product.	If a laser treatment device (laser surgical scalpel) or an electrosurgical device (electrical scalpel) is used in oxygen, sudden ignition, possible inhalation injury etc. due to ignition, and generation of toxic gas may occur.

3. Medical devices to be used in combination (Medical devices that can be used concomitantly)

Name	Specification
Ventilator and anesthetic device	Those connectable to the 15 mm male connector
Suction device Suction tube	Tube less than 75% of the inner diameter of each cannula

4. Drugs to be used in combination (Drugs that can be used concomitantly)

Name	Nonproprietary name
Water-soluble lubricant, anesthetic	Lidocaine 2%
Medical oxygen	Oxygen

< Defects and adverse events >

Other defects

[1] Cutting of the tubes.
[Cut due to the following causes.]
- Damage caused by tweezers, forceps, scissors, scalpel, or other instruments.
- Sudden load on the product due to self (accidental) removal, etc.
- Other complex causes due to factors such as the above events.

[2] Loosening or coming off of the connection with the respiratory circuit.
[The connection between the product and the respiratory circuit may be loosened or come off due to deformation of the connector, abnormal connection condition etc.]

Other adverse events

When performing tracheostomy, the following adverse events are generally expected.

[1] Adverse events during intubation.
Bleeding and tracheal injury due to compression and contact by the tracheostomy tube.

[2] Adverse events during the tube placement.
Respiratory narrowing and obstruction of lumen of cannula due to dislocation of the tracheostomy tube, and poor ventilation caused by respiratory obstruction due to inflow of secretions or blood etc., pneumothorax, subcutaneous emphysema, infection, granulation, inability of ventilation due to poor fit of the connector with the ventilator, and burn due to local high-frequency heating.

[3] Adverse events during extubation.
Aspiration, pulmonary edema, pneumothorax, tracheal narrowing and necrosis of the cricoid cartilage.

[4] If a laser surgical unit or an electrosurgical device are used in the vicinity of the product, the product may burn suddenly if it comes in contact with the laser beam or an electrode, causing burn injury, etc.

[5] Obstruction of the swivel connector.
Obstruction of the swivel connector may cause dyspnea, cyanosis, etc.

[6] Remnant in the body due to cutting of the cannula.

< Other Precautions >

When the product is to be used outside the hospital, healthcare professionals must explain the methods of safe of use and operations to the person handling the product.

【STORAGE METHOD AND DURATION OF USE】

< Storage method >

Store the product cleanly. Avoid wetting, direct sunlight, high temperature and humidity, and ultraviolet rays such as germicidal lamp, etc.

< Duration of use >

The product has been developed for "use within 29 days".
[Based on self-certification (our company data).]

< Expiration date >

When the proper storage method has been maintained, refer to the expiration date on the individual package.
[Based on self-certification (our company data).]

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