All Silicone Tracheostomy Tube (Cuffed)

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 [7] 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 >

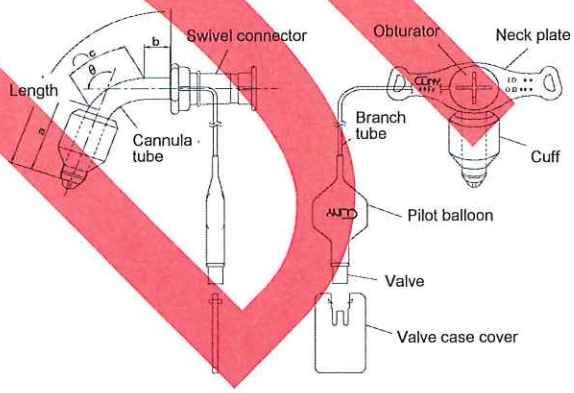
Do not connect the product to a connector of the Norman Elbow type (shape with the inner cylinder for gas supply inside the connector protrudes toward the patient). For details, see **< Interactions (concerning to be used in combination with other drugs or medical devices etc.) >** in **[PRECAUTIONS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

[SHAPE, STRUCTURE, AND PRINCIPLE]

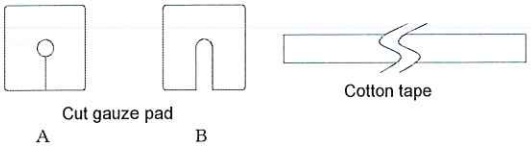
The product is sterilized with ethylene oxide gas.

< Shape >

- Tracheostomy tube (Cuffed)



- 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

Size (inner diameter)	Cuff diameter when inflated at 2kPa (mm)	Air injection volume in the cuff for pre-check
5.0	15	4 mL
6.0	17	5 mL
7.0	19	7 mL
7.5	23	11 mL
8.0	23	11 mL
8.5	23	11 mL
9.0	23	13 mL
9.5	26	15 mL

< Raw materials >

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

< Principle >

Fenestrate the trachea to insert the product. Inject air into the cuff, then fix and place the cuff 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., a syringe (5 or 10 mL), cuff pressure gauge, 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] Remove the valve case cover before use.
Hold the valve case cover and the valve firmly as shown in Figure 1. Keep the valve case cover horizontally as shown in Figure 2, and fold the valve downward until it comes off from the valve case cover.
Discard the valve case cover after removal.


Figure 1


Figure 2

[5] Inject air into the pilot balloon of the tracheostomy tube to check that the cuff inflates normally. After checking the inflation state of the cuff, remove air from the cuff completely.

[6] Properly position the patient for operative procedure.

[7] Disinfect the surgical site with disinfectant.

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

[9] Insert the dilatation forceps.

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

[11] 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.

[12] Connect a syringe to the valve, and inflate the cuff gradually until the noise of air leakage fades away completely on tracheal auscultation. Alternatively, inflate the cuff to an appropriate pressure using a cuff pressure gauge.

[13] 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.

[14] 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.

[15] 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] Suction the depot in the upper cuff and remove air from the cuff.

[3] Extubate slowly.

< Replacement method >

[1] Check the product, etc. according to [2] to [5] 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] Connect a syringe to the valve, and inflate the cuff gradually until the noise of air leakage fades away completely on tracheal auscultation. Alternatively, inflate the cuff to an appropriate pressure using a cuff pressure gauge.

[6] 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.

[7] 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] When taking out the product after opening, be careful not to damage the cuff, etc.

[2] Do not pull the valve case cover forcibly to remove it.
[If it is pulled out forcibly, the pilot balloon and the branch tube may be damaged.]

[3] Make sure to discard the valve case cover once it is removed. Do not reattach it to the valve or use it for any other purposes.
[The valve case cover is a part that releases the valve stopper to reduce the load on the cuff during sterilization. If it is reattached after intubation and injection of air, air in the cuff may be leaked.]

[4] Check the cuff, the branch tube, the pilot balloon and the valve for any defects (leakage or occlusion) before use.

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

[6] During insertion, be careful not to damage the pilot balloon or cuff with the apparatuses used (forceps, etc.) or protrusions in the body (cartilage, etc.).

[7] Please note the following when injecting air into the cuff and remove air from the cuff.
1) Use air for cuff inflation and inject air slowly and carefully.
2) For the cuff inflation, use a general slip-type disposable syringe.
[Luer lock-type syringe cannot be inserted into the end of the valve firmly. And using a syringe with unfitted taper may cause breakage of the valve.]
3) Use a clean syringe or cuff pressure gauge to prevent contamination of the valve with foreign matters.
[Foreign matters (dried body fluid or lint, etc.) may be caught in the valve, failing to inflate the cuff.]
4) Insert the tip of the syringe or cuff pressure gauge firmly to the valve.
[If the insertion is shallow, it may not be possible to inject or remove air.]
5) When removing the syringe, make to hold the valve, and remove the syringe by rotating it.
[In rare cases, the valve may be dislocated or come off.]
6) When deflating the cuff, operate the syringe slowly.
[If the syringe is operated rapidly, the cuff may stick to the cuff hole and prevent remaining air in the cuff from removing.]

[8] Check the cuff pressure periodically with a cuff pressure gauge etc. and control it appropriately during injection of air into the cuff and using.

[9] Control the internal pressure of the cuff with the minimum air injection volume to seal the trachea.
[Injection of excessive air into the cuff may cause damage to the cuff and tracheal damage or necrosis.]

[10] 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.

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

[12] To manage the airway 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] After suctioning, confirm that the internal pressure of the cuff and the respiratory management state are appropriate.

[7] 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.]

[8] Do not pull the branch tube and the pilot balloon.
[It may cause failure or leakage.]

[9] Do not connect a three-way stopcock or an extension tube for infusion, etc. to the valve of the pilot balloon.
[The valve may be damaged during removal of a three-way stopcock etc., and it may become impossible to injection of air into or removal of air from the cuff.]

[10] Before measuring the internal pressure of the cuff, make sure that no liquid is accumulated in the branch tube and the pilot balloon, etc.
[Condensation of water vapor that penetrated the cuff membrane inside the cuff has been reported. It may be sealed by water droplets condensed in the branch tube, preventing accurate measurement of the internal pressure of the cuff.]

[11] Before insertion, removal and repositioning of the product, remove air from the cuff completely.
[The trachea and tracheostomy stoma may be damaged.]

[12] Before removing air from the cuff, suction secretions that have accumulated on the upper cuff.
[During removal of air from the cuff, secretions may flow into the lungs.]

[13] If air cannot be removed from the cuff, cut the branch tube, and remove air.

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

[15] 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.

[16] 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.]

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

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

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

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

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

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

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

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

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

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

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

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

[29] 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.
Magnetic Resonance Imaging (MRI)	Keep the valve of the product outside the MRI scanning area.	The spring in the valve may affect the image.
Hyperbaric oxygen therapy equipment	Pay attention to deflation and inflation of the cuff.	There are risks of air leakage and tracheal damage.

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

Name	Specification
Syringe	-Slip type -Volume: 5 ~ 10 mL
Ventilator and anesthetic device	Those connectable to the 15 mm male connector
Suction device	Tube less than 75% of the inner diameter of each cannula
Suction tube	
Cuff pressure gauge	Tip shape: Slip type shape

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] Burst of the cuff.
[Burst due to the following causes.]
- Damage caused by tweezers, forceps, scissors, scalpel, or other instruments.
- Excessive injection volume (overexpansion).
- Injection of a substance other than air for inflation of the cuff.
- Sudden load on the product due to self (accidental) removal, etc.
- Other complex causes due to factors such as the above events.

[2] 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.
- Load by twisting, etc.
- Other complex causes due to factors such as the above events.

[3] Impossibility of cannula removal. (If the cuff cannot be deflated, under the guidance of a physician, cut the branch tube to remove air.)

[4] 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.]

[5] Valve breakage or leakage.
[Valve breakage or leakage may occur due to local high-frequency heating.]

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] Inappropriate air volume.
If air injection volume in the cuff is inappropriate, it may cause injury of the tracheal wall and inflow of secretions (saliva etc.) to the trachea.

[5] 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.

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

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

< Other precautions >

[1] When performing anesthesia using a gas mixed with nitrous oxide, pay attention to deflation and inflation of the cuff.
[Tracheal damage due to increased internal pressure of the cuff caused by penetration of nitrous oxide into the cuff has been reported.]

[2] 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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