GB

TRACHEAL TUBES - INSTRUCTIONS FOR USE

Pictograms

REF	Catalogue number		Manufacturer	PHT DEHP	Free from phthalates (incl. DEHP)
LOT	Batch code	UDI	Unique device identifier		Do not use if packaging is damaged
	Date of manufacture	LATEX	Free from latex	2	Do not re-use
	Use-by date		Consult instructions for use		Keep dry
CE 1011	CE marking with Notified Body no.		Keep away from sunlight	40°C 5°C	Temperature limit 5-40°C
STERILE EO	Sterilized using ethylene oxide, Single sterile barrier system		MD	Medical device	

These instructions for use refer to the following products:

Tab. no 1	
02-XXXX	12-XXXX
04-XXXX	13-XXXX
05-XXXX	14-XXXX
06-XXXX	25-XXXX
07-XXXX	26-XXXX
08-XXXX	27-XXXX
11-XXXX	28-XXXX

Description

Assortment of sterile, single-use tracheal tubes, to be used through mouth/nose, manufactured of pure polyvinyl chloride (PVC) is characterized by the following properties:

1. Anatomically designed shape with adequately shaped curvature, with a radiation line for confirmation of a correct position of the tube using Roentgen rays.
2. In the tubes with a cuff: a low pressure sealing cuff and a testing balloon with a non-return valve.
3. All the tracheal tubes are equipped with a 15 mm connector.
4. They are sterile ones until opening or damaging of their package.
5. Reinforcement in the wall of reinforced tube is aimed at elimination of creasing by the patient or a bend.

Indications

1. Required ventilation with positive pressure.
2. Administration of anaesthesia, where using of a face mask is impossible.
3. Protection against aspiration.
4. Removing of secretion from the trachea and bronchia by way of suction.
5. Application during surgical procedures of a head, neck and mouth, where it is favourable removal of all auxiliary elements from the surgical field – the shaped or reinforced tubes.

Contraindications

1. Tracheal stenosis
2. Abnormal anatomy of the airway
3. Magnetic resonance imaging use - applies to all reinforced tracheal tubes (reinforcement is made of metal) or cuffed tracheal tubes (contain a small metal element in the valve of the cuff inflation line).
4. Contact with electrosurgical electrodes or a laser - can result in PVC degradation accompanied by the release of toxic fumes, or even ignition in an oxygen-enriched environment.
5. Sensitization to components of the medical device

Instructions for use

1. To gently remove the sterile tracheal tube from the packaging.
2. To firmly mount the 15 mm connector in the tracheal tube.
3. Check if 15mm connector fits to breathing system.
4. Check the patency of the tube.
5. In the event of tubes with a cuff there should be checked the cuff and testing balloon as well as a valve of each tube by filling before use. To place the end-part of Luer syringe in housing of the inflation valve of the cuff and give an injection of air in the quantity sufficient to completely fill the cuff. The diameters of the cuffs are given in Tab. No 2.
6. After testing inflation of the cuff and affirmation of its air-tightness, deflate it completely.
7. If a stylet is required for the tracheal tube positioning, verify the compatibility between the stylet and the tube, following the recommendations in the stylet's instructions for use.
8. When inserting the stylet, check the compatibility of the stylet and the tube, paying particular attention to the ease of insertion of the stylet into the tube.
9. In case of a tube provided with an already inserted stylet, ensure that the stylet can be easily removed from the tube prior to intubating the patient.
10. After inserting the stylet into the tracheal tube (the tube may be preheated), shape the tube according to the patient's anatomy.
11. Do not heat the tracheal tube with the stylet inserted into it!
12. To intubate the patient through the mouth or nose paying attention to observance of current approved medical techniques. A marker of intubation depth may be of help to you in making corrections of the tube's arrangement. The diameters of the cuffs are given in Tab. No 2.
13. Hold the tube by the connector and then gently slide out the stylet.
14. Do not use excessive force to remove the stylet.
15. If removal of stylet from the intubated tube proves difficult, extubate the tube with stylet still inserted into it, and replace them with a new set, rather than attempting to separate them.
16. To inflate the cuff with a minimal quantity of air sufficient to cause efficient tightness.
17. To remove the syringe from the housing of inflation valve after inflation of the cuff. Leaving of the syringe will cause opening of the valve and deflation of the cuff.
18. Pressure in the cuff should be under routine monitoring and adjustment.
19. The cuff should be protected against contact with sharp edges.
20. Before removal of the tube from the trachea deflate the cuff inserting of the syringe into the housing of valve and removing of air until you can observe that the pilot balloon is completely collapsed.
21. Extubate the patient following currently approved medical techniques.
22. Throw the tracheal tube aside. Consideration should be given to the specific warnings announced in the instructions for use

Recommended remedial actions in the case of airway obstruction during Tracheal Tube use:

1. Immediately deflate the cuff and make an attempt to reestablish ventilation.
2. If ventilation cannot be restored:

a. Remove the tracheal tube from the patient's trachea.
b. Use bag-valve-mask or laryngeal mask to restore ventilation.
c. Reintubate patient with a new tracheal tube, or if surgically necessary, reintubate with a new, larger tracheal tube, that allows for reduction of cuff pressure.

Precautions

1. A physician should take proper precautions in order to avoid potential damage of the tracheal cuff as a result of its contact with the patient's teeth or all kind of tools having sharp edges, constituting a threat for integrity of the cuff.
2. One should not use a tube with a damaged cuff.
3. Do not use lubricants when inserting the 15 mm connector in the tracheal tube, as this may cause it to disconnect later.
4. Use of lidocaine spray is associated with formation of pinholes in the PVC cuff.
5. Do not measure the inflation of the cuff by the volume of air introduced or the resistance you feel when inflating. Nitrous oxide can diffuse into the cuff during anaesthesia, causing increased pressure in the cuff.
6. Changes in patient position and/or tube position after intubation should be observed and the correct position of the tracheal tube should be verified immediately. Deflate the cuff before repositioning the tube. Moving the tube with an inflated cuff may result in injury to the patient requiring medical intervention or damage to the cuff
7. Do not overinflate the cuff. Ordinarily, the pressure in the cuff should not exceed 25 cm H_2O. Overinflation can result in tracheal damage, rupture of the cuff with subsequent deflation or cuff distortion, which consequently may lead to airway blockage.
8. If excessive bending of the patient's head or significant patient movement occurs after intubation (e.g. down to lateral recumbent position or prone position) it is advisable to consider using a reinforced tube for intubation.
9. If a tracheal tube was lubricated prior to use, it is essential to inspect whether the lubricant has entered and obstructed the lumen of the tube, leading to ventilation blockage or cuff damage.

Complications

Due to the potential risk of airway infection from certain treatment-resistant hospital strains, it is crucial to adhere to currently approved medical procedures and techniques. Resterilization or reuse may pose a risk to the patient, as the tube is intended for single use only. Following approved medical techniques and having the procedure performed by qualified medical personnel minimizes the likelihood of complications e.g.:
sore throat, lacerations to the lips, gums or other structures in the upper respiratory tract, chipped, broken or displaced teeth, nosebleeds, corneal lacerations, laryngospasm, pulmonary aspiration of gastric contents or other foreign bodies, paralysis of the vocal cords due to paresis of the recurrent laryngeal nerve , decreased blood oxygen saturation and increased arterial carbon dioxide concentration, damage to the vocal cords, dislocation of the arytenoid cartilage, damage to the tonsils and potentially serious epistaxis, obstruction of the endotracheal tube (cuff hernia), ulceration of the supra- and subglottic area, damage to the vocal cords, perforation of the esophagus , pharynx, trachea, bronchial intubation, laryngeal or tracheal stenosis, laryngeal spasm, subglottal edema, pulmonary edema (fluid in the lungs), aspiration, unrecognized esophageal intubation, reflex reactions from the vagus nerve or spinal cord, tracheoesophageal fistula, respiratory tract obstruction due to loss of tracheal stiffness, ventilator-associated pneumonia, narrowing of the glottis or trachea

Notes

1. Tracheal tubes should be stored in room conditions.
2. Do not use in case of damage packaging.
3. Do not use after the use-by date.

DISPOSAL

After use, dispose this device following the relevant national regulations for the disposal of medical waste.

Responsibility – legal guidelines

The tracheal tubes manufactured by SUMI are subjected to physical and chemical testing and bio-compatibility testing. This allows their safe use and ensures highest quality. Carefully read the instructions for use before using the medical device. Tracheal tubes made by SUMI are intended for use only by qualified medical personnel and trained patients (users). The SUMI company will not be liable for the consequences caused by improper selection of tube size or by misuse of the tubes contrary to its intended purpose or provided instructions for use.
In the event of a complaint or an occurrence of a medical incident, keep the medical device with its primary packaging. It is also recommended to create photographic documentation. Every Medical Incident have to be reported to the Manufacturer and relevant National Competent Authority.

Tab. no 2				
Size [mm]	Length of the line [mm] (for the tubes without a cuff) 04-xxxx, 07-xxxx	Diameter of the cuff [mm] 02-xxxx, 11-xxxx 12-xxxx, 25-xxxx, 27-xxxx	Diameter of the cuff [mm] 06-xxxx, 08-xxxx	Diameter of the cuff [mm] 05-xxxx
2,0	20	7		
2,5	20	8		
3,0	20	8		
3,5	20	10		
4,0	30	10		20
4,5	30	12		
5,0		14	20	25
5,5		17	20	
6,0		20	25	28
6,5		20	25	
7,0		23	28	
7,5		25	28	
8,0		26	30	
8,5		26	30	
9,0		29	34	
9,5		32	34	
10,0		32	34	

SUMI spółka z ograniczoną odpowiedzialnością sp. k.
ul. Drobiarska 35, 05-070 Sulejówek, Poland
tel/fax (+48 22) 783 30 23 www.sumi.com.pl

Ed. no 12 04.04.2024.