INSTRUCTIONS FOR USE

Doc. No.: SSIPL/IFU/TT/01, Rev. No.:00, Date:12.08.2023

NAME OF PRODUCT: Tracheostomy Tube

PRODUCT CODE: SMD 702 P, SMD 702 C, SMD 702 IC, SMD 702 F and SMD 702 S

PRODUCT DESCRIPTION:

Tracheostomy Tube Plain (SMD 702 P):

A curved PVC hollow tubular device inserted into the artificial opening made in the throat after a tracheotomy, to secure the airway. The device is used by persons who have been operated because of a restricted airway passage and will guarantee the airway patency and facilitate rapid aspiration of secretions. It is intended for short term use.

Tracheostomy Tube Cuffed (SMD 702 C):

A curved PVC hollow tubular device inserted into the artificial opening made in the throat after a tracheotomy, to secure the airway. The device is used by persons who have been operated because of a restricted airway passage and will guarantee the airway patency and facilitate rapid aspiration of secretions. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevent leakage of gases. It is intended for short term use.

Tracheostomy Tube Cuffed with Inner Cannula (SMD 702 IC):

A curved PVC hollow tubular device inserted into the artificial opening made in the throat after a tracheotomy, to secure the airway. The inner cannula fits inside the trach tube and acts as a liner. This liner can be removed and cleaned to help prevent the build-up of mucus inside the trach tube. The inner cannula locks into place to prevent accidental removal. The device is used by persons who have been operated because of a restricted airway passage and will guarantee the airway patency and facilitate rapid aspiration of secretions. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevent leakage of gases and hollow inner cannula. It is intended for short term use.

Tracheostomy Tube Cuffed with Inner Cannula & Fenestrated with speaking valve (SMD 702 F):

A curved PVC hollow tubular device inserted into the artificial opening made in the throat after a tracheotomy, to secure the airway. Fenestrated tracheostomy tubes are used to allow for increased airflow for voicing. When the cuff is inflated, they can allow for some airflow to pass through the fenestrations to allow for speech. The device is used by persons who have been operated because of a restricted airway passage and will guarantee the airway patency and facilitate rapid aspiration of secretions. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevent leakage and extended tube patient end with fenestration. It is intended for short term use.

Tracheostomy Tube Cuffed with Subglottic Suction (702 S):

A curved hollow PVC tubular device inserted into the artificial opening made in the throat after a tracheotomy, to secure the airway. The device is used by persons who have been operated because of a restricted airway passage and will guarantee the airway patency and facilitate rapid aspiration of secretions. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevent leakage and provided Suction port used to remove secretions from above the cuff while leaving the tube in position. It is intended for short term use.

INTENDED PURPOSE:

Tracheostomy inserted into the artificial opening made in the throat after a tracheotomy, to secure the airway patency and used for short term.

INDICATIONS :

- Acute respiratory failure and need for prolonged mechanical ventilation (representing two thirds of all cases)

- Traumatic or catastrophic neurologic insult requiring airway, or mechanical ventilation or both.
- Upper airway obstruction

CONTRAINDICATIONS:

- Active cellulitis of the anterior neck skin
- High Ventilatory/positive end-expiratory pressure (PEEP) requirements
- History of neck surgery and throat cancer.
- Injury to the nerve that moves the vocal cords (recurrent laryngeal nerve).

INTENDED USER:

Trained and registered health care professional.

INTENDED PATIENT POPULATION:

Infants, Paediatrics and Adults

WARNINGS, CAUTIONS AND PRECAUTIONS:

- The use of this product is restricted to a Doctor or a qualified Paramedic.
- Read instructions before use and should be used according to the instruction for use.
- **STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUANCES FROM IMPROPER USE.**
- The product should be used immediately after open the packing.
- The product is Guaranteed Sterile if the package has not been opened or damaged.
- Do not clean or Re-sterilize.
- For single patient use only and discard after use.
- A spare Tracheostomy Tube of the correct size should be kept readily available.
- Use only water soluble lubricants with this tube.
- Ensure the tube is securely attached to the neck and fully inserted into the stoma.
- Check the security of 15 mm male connectors frequently to prevent accidental disconnection.
- Do not use excessive force when connecting the respiratory circuit to the tracheostomy tube connector.
- **Monitor cuff pressure more frequently during anesthesia because nitrous oxide diffuses through the cuff wall and increase the cuff pressure that could result in tracheal pressure trauma.**
- Cuff volume should be routinely monitored and adjusted. Over-inflation of the cuff may result in permanent tracheal damage and restricted ventilation.
- **Do not use device in the patients intended for laser beam or electrosurgical electrode surgical procedure. During such procedure Tracheostomy Tube can result a sudden ignition in the presence of mixtures of nitrous oxide and oxygen or pure oxygen.**
- **Tracheostomy Tube Cuffed are MRI Conditional and Items may safely enter into the MRI scanner room only, patient should not be scanned unless the device is positively identified as MRI conditional and the condition for safe use are met.**
- **In the event of change in performance of device observed and same is reflected in ventilator circuit the tube should be replaced.**
- Avoid repositioning the tube while the cuff is inflated to prevent tracheal trauma.
- Prior to cuff deflation and tube removal, remove any secretions that may have accumulated above the inflated cuff to prevent aspiration.
- Prior to insertion or removal, the cuff must be completely deflated to prevent tracheal damage.
- Avoid pulling on the cuff inflation line. Maintain the inflation line in a position allowing for patient mobility without placing tension on the inflation line-to-tube junction.

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- After inflation of the tracheal cuff, disconnect the syringe from valve. Leaving the syringe attached will keep the valve open, permitting air to come out. The inflation condition of the tracheal cuff should be monitored at all times. Due to gas diffusion through the cuff, the internal cuff pressure (or inflation volume) changes over time. If inflation or deflation of the cuff is required, be sure to first evacuate the air completely from the cuff (until pilot balloon is also collapsed) first and then inflate the cuff again to the appropriate volume.
- Before intubation or extubation, adjust the tracheal cuff position, to be sure to evacuate air completely from the cuff (until pilot balloon is also collapsed). Otherwise, it may damage the cuff or may be traumatic to the patient's trachea.
- Store in a Cool and dry place.
- Do not expose to heat or direct sunlight.

INSTRUCTIONS FOR USE:

- Carefully check the product and packaging before use, improper transport and handling may cause structural and functional damage to Device or packaging.
- **For Cuffed Tubes, a Leak Test Must be Performed Prior to Use.**
- Using aseptic technique and just prior to insertion, lubricate both the obturator and patient end (distal) of the tube with a water soluble lubricant. Slide the lubricated obturator though the cannula to ensure sufficient lubrication and ease of obturator movement.
- Always select the largest tube size that will accommodate the patient’s anatomy to ensure optimal ventilation.
- Surgically perform stoma in trachea through throat.
- Insert the tube with obturator into the patient’s stoma and immediately remove the obturator.
- For Cuffed Tubes Only: If a tracheal seal is desired, Insert syringe into one way valve and inflate the cuff until suitable seal can be reached. Do not over inflate the cuff with air.
- Confirm proper tube placement and secure the neck flange to the patient’s neck with the twill neck strap provided, taking care to thread the twill through the eyelets. Do not tie a knot directly in the eyelet.
- When connecting to respirator, make sure the 15mm connector is firmly attached to the respiratory circuit.
- Cuff pressure should be monitored after intubation.
- The patient’s respiration should be routinely evaluated after inserting the tracheostomy tube to ensure the airway through the tube is unobstructed.
- For Cuffed Tubes Only: Prior to removal of the tube, remove any secretions that may have accumulated above the inflated cuff. Slowly remove the entire air from the cuff until the pilot balloon is completely deflated.
- Extubation should be performed following currently accepted medical techniques.
- Discard the Endotracheal Tube after use.

ADVERSE EFFECTS:

- Bleeding
- Pneumothorax
- Infection
- Pressure necrosis
- Necrosis due to ischemia

CLINICAL BENEFITS:

- Improved patient comfort
- More effective airway suctioning
- Decreased airway resistance
- Enhanced patient mobility
- Increased opportunities for articulated speech
- The ability to eat orally, a more secure airway
- Accelerated weaning from mechanical ventilation

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- Tracheotomy tube resulted in both potential benefits for swallowing success
- Improved patient communication, rehabilitation participation, mobilization
- Reduced sedation

RESIDUAL RISKS:

- Pneumonia
- Pneumothorax
- Damage, scarring or narrowing of the trachea, Infection around the tracheostomy or infection in the trachea, damage to esophagus

SUPPLY:

Tracheostomy Tube Plain - SMD 702 P	
Tracheostomy Tube Cuffed - SMD 702 C	
Tracheostomy Tube Cuffed with Inner Cannula - SMD 702 IC	
Tracheostomy Tube Cuffed with Inner Cannula & Fenestrated with speaking valve - SMD 702 F	

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Tracheostomy Tube Cuffed with Subglottic Suction - SMD 702 S	

MATERIAL USED:

Device Variant	Component	Material	Specification/ Material Grade
Tracheostomy Tube Plain (SMD 702 P):	PVC Tube	Polyvinyl Chloride	Medical Grade
	Radiopaque Line	Polyvinyl Chloride	Medical Grade
		ROP Granules	Medical Grade
		Pigment Blue	Medical Grade
	15 MM Bush	Acryl Butadine Styrine (ABS)	Medical Grade
		Polypropylene	Medical Grade
	Neck Flange	Polyvinyl Chloride	Medical Grade
	Obturator	Polypropylene (PP)	Medical Grade
Tracheostomy Tube Cuffed All Variant (SMD 702 C):	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Obturator	Polypropylene (PP)	Medical Grade
		LDPE	Medical Grade
	Neck Flange	Polyvinyl Chloride	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	Polypropylene (PP)	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Bush	Acryl Butadine Styrine (ABS)	Medical Grade
		Polypropylene	Medical Grade
	Pigment	Blue, White & Purple	Medical Grade
Tracheostomy Tube Cuffed with Inner Cannula (SMD 702 IC):	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Obturator	Polypropylene (PP)	Medical Grade
	Inner Cannula	Polypropylene (PP)	Medical Grade
	Neck Flange	Polyvinyl Chloride	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	Polypropylene (PP)	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Bush	Acryl Butadine Styrine (ABS)	Medical Grade
	Pigment	Blue, White & Purple	Medical Grade
Tracheostomy Tube Cuffed with Inner Cannula & Fenestrated with speaking valve (SMD 702 F):	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Obturator	Polypropylene (PP)	Medical Grade
	Inner Cannula	Polypropylene (PP)	Medical Grade
	Neck Flange	Polyvinyl Chloride	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	Polypropylene (PP)	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Bush	Acryl Butadine Styrine (ABS)	Medical Grade
	Speaking Valve	Polypropylene (PP)	Medical Grade

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	Body		
	Speaking Valve Body Cover	Polypropylene (PP)	Medical Grade
	Speaking Valve Valve	Silicone	Medical Grade
	Pigment	Blue, White & Purple	Medical Grade
Tracheostomy Tube Cuffed with Subglottic Suction (SMD 702 S):	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Obturator	Polypropylene (PP)	Medical Grade
	Neck Flange	Polyvinyl Chloride	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	Polypropylene (PP)	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Bush	Acryl Butadine Styrine (ABS)	Medical Grade
	Suction Tube	Polyvinyl Chloride	Medical Grade
	Suction Port	Polyvinyl Chloride	Medical Grade
	Pigment	Yellow, White & Purple	Medical Grade

STERILITY:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused devices.

STORAGE:

The Device should be stored in their original box in a cool and dry place between 5 to 45° C, preferably away from direct and indirect sources of light and heat. Do not use after expiry.

DEVICE DISPOSAL:

Used Devices may be contaminated with infectious and/or other hazardous materials. Unused expired devices should be disposed of as per local regulations.

NOTE:

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

SPECIMEN SYMBOL

SYMBOL	DESCRIPTON	SYMBOL	DESCRIPTON	SYMBOL	DESCRIPTON	SYMBOL	DESCRIPTON
	**Catalogue No.**		**Batch / Lot No.**		**Date of Mfg.**		**Date of Exp.**
	**Cautions**		**See instructions for Use**		**Sterilized by Ethylene Oxide gas**		**Do not Re-sterilize**

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	**Do not use if packaging is damaged or Opened**		**Phthalate Free**		**Medical Device**		**Avoid Direct Sunlight**
	**Do not Reuse**		**MRI Conditional**		**CE Certification**		**Sterile Barrier System**
	**Keep Dry**		**Pyrogen Free**		**Temperature limit is 5°C to 45°C**		**Unique Device Identifier**

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