INSTRUCTIONS FOR USE

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

NAME OF PRODUCT: Endotracheal Tube

PRODUCT CODE: SMD 701 P, SMD 701 C, SMD 719 P, SMD 719 C, SMD 717, SMD 717 C, SMD 718 S, SMD 718 SC, SMD 754, SMD 722, SMD 701 SP, SMD 701 SC, SMD 765, SMD 701 CT, SMD 772 and SMD 701 M

PRODUCT DESCRIPTION:

Endotracheal Tube Plain (SMD 701P):

A Plain PVC Endotracheal Tube is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. It is intended for short term use.

Endotracheal Tube Cuffed (SMD 701C):

A Cuffed PVC Endotracheal Tube is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases. It is intended for short term use.

Reinforced Endotracheal Tube Plain (SMD 719 P)):

A Reinforced Plain PVC Endotracheal Tube is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is having reinforced spiral SS wire in the wall thickness of tube which makes it kink resistance and difficult to crush by the patient during use. It is intended for short term use.

Reinforced Endotracheal Tube Cuffed (SMD 719 C):

An Reinforced Cuffed PVC Endotracheal Tube is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases. Also the tube is having reinforced spiral SS wire in the wall thickness of tube which makes it kink resistance and difficult to crush by the patient during use. It is intended for short term use.

Endotracheal Tube Preformed North Nasal Plain (SMD 717):

A PVC ET Tube Preformed (North Nasal Plain) is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is preformed to meet the specific requirements of patients undergoing facio-maxillary surgery. It is intended for short term use.

Endotracheal Tube Preformed North Nasal Cuffed (SMD 717 C):

A PVC ET Tube Preformed (North Nasal Cuffed) is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases. The tube is preformed to meet the specific requirements of patients undergoing facio-maxillary surgery. It is intended for short term use.

Endotracheal Tube Preformed South Oral Plain (SMD 718 S):

A PVC ET Tube Preformed (South oral Plain) is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is preformed to meet the specific requirements of patients undergoing head, nasal. ophthalmic and facial surgery. It is intended for short term use.

Endotracheal Tube Preformed South Oral Cuffed (SMD 718 SC):

A PVC ET Tube Preformed (South oral Cuffed) is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is provided with a cuff which

make seal between cuff and tracheal wall after inflation to prevents leakage of gases. Also the tube is preformed to meet the specific requirements of patients undergoing head, nasal. ophthalmic and facial surgery. It is intended for short term use.

Endotracheal Tube Cuffed with Subglottic Suction (SMD 722):

A Cuffed PVC Endotracheal Tube is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases and the Suction port is used to remove secretions from above the cuff while leaving the tube in position. It is intended for short term use.

Endotracheal Tube Preformed Pearl/Ivory Nasal (SMD 754):

A PVC ET Tube Preformed (North Nasal Cuffed) is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases. The tube is preformed to meet the specific requirements of patients undergoing facio-maxillary surgery. It is intended for short term use.

Endotracheal Tube Plain Silicone Elastomer Coated (SMD 701 SP):

A Silicone Elastomer coated Plain PVC Endotracheal Tube is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. Silicone Elastomer coating preventing stucking of ET Tube into trachea. It is intended for short term use.

Endotracheal Tube Cuffed Silicone Elastomer Coated (SMD 701 SC):

A Silicone Elastomer coated Cuffed PVC Endotracheal Tube is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases. Silicone Elastomer coating preventing stucking of ET Tube into trachea. It is intended for short term use.

Endotracheal Tube Microlaryngeal Cuffed (SMD 765):

Microlaryngeal PVC ET tube is a small diameter single lumen ETT, which is used for microlaryngeal surgeries as it offers more working space to the surgeon. Its length is comparable to a standard ETT of 8 mm ID. These tubes have special low pressure, large volume, and large diameter cuff to protect the airway. It is intended for short term use.

Endotracheal Tube with Tapered Cuff/Treachseal (SMD 701 CT):

A PVC tracheal tube with a tapered cuff is designed to minimize longitudinal folds during inflation, improve the tracheal seal, and prevent the leak of secretions and air, even under high airway pressures. It is intended for short term use.

Endotracheal Tube Cuffed with Blue Tip (SMD 772):

A Soft Blue Tip Cuffed PVC Endotracheal Tube is designed to protect patient from trauma. It is used in general anesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs. The tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevents leakage of gases. It is intended for short term use.

Endotracheal Tube with Micro cuff (SMD 701 M):

Microcuff PVC Endotracheal Tube is specifically designed for the paediatric airway anatomy. Intubation depth marks and short, cylindrical PU cuff near tracheal tube tip allow adequate placement with a cuff-free subglottic zone, without the risk of endobronchial intubation. It is intended for short term use.

INTENDED USE:

Endotracheal Tube is inserted orally or nasally into the trachea to maintain airway patency and/or to deliver anaesthetic inhalation agents or other medical gases, and secure ventilation & used for short term.

INDICATIONS FOR USE:

- Surgery & Emergency situations (when a person is unable to breathe on their own)

- Lung disease
- Chest trauma or airway obstruction
- Severe pneumonia,
- Head injury,
- Collapsed lung,
- Respiratory failure,
- Congestive heart failure,
- Acute respiratory distress syndrome (ARDS)
- Other conditions that affect breathing

Note: All Plain variant is indicated to delicate trachea where cuffed tube pressure may cause trauma and cuffed tube is provided with a cuff which make seal between cuff and tracheal wall after inflation to prevent leakage of gases.

CONTRAINDICATIONS:

- Severe airway trauma or obstruction
- Severe cervical spine injury
- Facial trauma
- Head trauma
- Active epistaxis
- Expanding neck hematoma
- Oropharyngeal trauma

INTENDED USER:

Anaesthesiologist and Critical care intensivist

INTENDED PATIENT POPULATION:

Adults, Paediatrics, Infants

WARNINGS:

- When cutting the tube to length, do not cut close to the joint between the inflation line and the main body of the tracheal tube as blockage or leakage of the inflation system may occur.
- Do not use lubricants to assist the insertion of the 15mm connector into the tracheal tube as disconnection may occur.
- Prior to removal or repositioning of cuffed tracheal tubes, all air must be completely removed from the cuff to prevent trauma to the airway.
- If the tracheal tube is lubricated prior to insertion, ensure the lubricant does not occlude the lumen of the tube preventing ventilation of the patient. Anaesthetic jellies and lubricants have been associated with complete or partial occlusion of tracheal tubes.
- Do not over inflate the cuff. Over inflation can result in trauma to the airway and/or rupture of the cuff with subsequent deflation, distortion or airway blockage.
- Do not gauge the adequacy of cuff inflation on the basis of the volume of air introduced, or the level of resistance felt during inflation.
- During anaesthesia, nitrous oxide may diffuse into the cuff causing an increase in cuff volume.
- Contact with electrosurgery electrodes or laser surgery beams must be avoided because PVC will produce toxic fumes in air or ignite in an enriched oxygen environment (e.g. Anaesthesia).

PRECAUTIONS AND CAUTIONS:

- 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.

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- **STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUANCES FROM IMPROPER USE.**
- The product should not be reprocessed.
- Do not use local anesthetic gels or creams to lubricate the tube or apply topical anesthetics sprays on the vocal cords.
- Carefully check the product and packaging before use, improper transport and handling may cause structural and functional damage to Device or packaging.
- The product is Guaranteed Sterile if the package has not been opened or damaged.
- Do not clean or Re-sterilize.
- For single use only and discard after use.
- Store in a Cool and dry place.
- Do not expose to heat or direct sunlight.
- The product should be used immediately after open the packing.
- A spare Endotracheal Tube of the correct size should be kept readily available.
- **Reinforced Endotracheal tube 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.**
- Care must be taken to avoid occlusion at the tip part of Endotracheal Tube when applying lubricant.
- Thoroughly lubricate the entire cuffs including the tip at the endobronchial tube before intubation.
- Do not apply the petroleum base lubricants it may result in damage to the cuffs, or may be traumatic to the patient's trachea.
- 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.
- Do not over inflate the cuff.
- 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.
- The security of all breathing system connectors should be checked when the breathing circuit is established and frequently thereafter. Disconnection may be facilitated with the use of a disconnection wedge.
- Patients should be adequately humidified to minimise encrustation of the tracheal tube lumen and prevent tracheal mucosal damage.
- The patency of the tracheal tube lumen must be assured by regular suctioning Check routinely and replace as required to maintain a patent airway. Maximum recommended period of use 30 days.
- Cuff pressure and volume should be monitored and adjusted routinely.
- Devices used in/during inflation of the cuff must be clean and free from all foreign matter. The inflation device must be removed from the inflation valve immediately after use.
- Guard against cuff damage by avoiding contact with sharp edges. If cuff is damaged, patient should be re-intubated and the damaged tube discarded.
- The inflation line valve may interfere with Magnetic Resonance Imaging (M) picture clarity. Ensure the valve is positioned away from the area being scanned.
- Repositioning and movement of the in-situ tracheal tube, while the cuff is inflated, should be avoided.
- In the event that unusual positioning of the head or neck is to be required following intubation, use of a reinforced tube should be considered to avoid the potential for kinking.
- Following intubation, the tracheal tube should be properly secured to help eliminate undesirable movement.
- Follow standard infection control procedures as specified by the Centre for Disease Control and Prevention (USA), or local equivalent.
- The use of a typical aerosol anaesthetic agent has been associated with the formation of pin holes in PVC Cuffs.
- When the patient's position is altered after intubation it is essential to verify correct tube position.
- A bite block should be used in cases where the patient may bite down and flatten the tracheal tube resulting in blockage.

- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Dispose of this product in a safe manner according to local guidelines for disposal of contaminated waste.

- Follow universal precautions as specified by the Centres for Disease Control and Prevention (USA).

INSTRUCTIONS FOR USE:

- Choose suitable tracheal tube according to the patient's age, sex, stature and bodily form, etc.
- Check for defects such as air leakage or odd expansion by injecting air into the cuff individually using a syringe.
- After checking the cuff, completely withdraw all air from tracheal cuff and remove the syringe from the valve.
- Conduct inflation test for the tracheal cuff prior to use. In case any malfunction such as air leakage or balloon herniation has occurred, the tube should not be used.
- Position your body correctly, raise patient's head backwards and keep mouth, pharynx and trachea as a line to expose larynx and glottis, and aim tracheal tube at glottis and put tube under glottis and for 4~5cm gently while patient finish breathing.
- Put in tooth pad to fetch out laryngoscope and extrude with breath cuffed tube and check breath sound of both lungs with stethoscope if it symmetrical, and adjust depth to pour 5ml. air in the cuffed tubes. Fix tube and tooth pad to avoid surging.
- Insert syringe into one way valve and inflate the cuff until suitable seal can be reached. Do not over inflate the cuff with air.
- When connecting to respirator, make sure the 15mm connector is firmly attached to the respiratory circuit.
- Cuff pressure should be monitored after intubation.
- Extubation should be performed following currently accepted medical techniques.
- Discard the Endotracheal Tube after use.

ADVERSE EFFECTS:

- Bleeding
- Infection
- Perforation of the oropharynx
- Hoarseness (vocal cord injury)
- Damage to teeth/lips

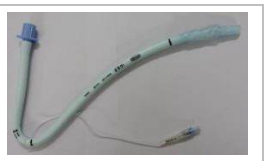
CLINICAL BENEFITS:

- Rapid and accurate confirmation of ETT placement.
- ETTs are safe
- Better intubating conditions
- Improved the laryngeal view
- Better patient outcomes
- Useful in the management of patients with restrictive and obstructive airway lung diseases.

RESIDUAL RISKS:

- Aspiration pneumonia
- Hypoxia, Lung collapse, Tracheal stenosis
- Infection, Laryngeal / Vocal cord injury

SUPPLY:

Plain - SMD 701 P		Preformed (Pearl Nasal) - (SMD 754)	

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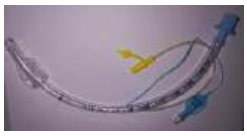
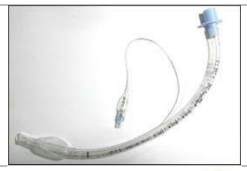
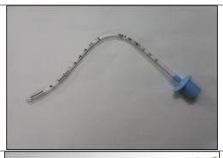
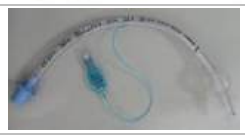
Cuffed - SMD 701 C		With Subglottic Suction - (SMD 722)	
Reinforced Plain - SMD 719 P		Plain Elastomer Coated - SMD 701 SP	
Reinforced Cuffed - SMD 719 C		Cuffed Elastomer Coated - SMD 701 SC	
Preformed (North Nasal Plain) - SMD 717		Microlaryngeal Cuffed - SMD 765	
Preformed (North Nasal Cuffed) - SMD 717 C		With Tapered Cuff/Treachseal - SMD 701 CT	
Preformed (South Oral Plain) - SMD 718 S		Cuffed with Blue Tip - SMD 772	
Preformed (South Oral Cuffed) - SMD 718 SC		With Micro cuff - SMD 701 M	

MATERIAL USED:

Product	Component	Raw Material	Specification / Material Grade
Endotracheal Tube Plain All Variants	PVC Tube	Polyvinyl Chloride	Medical Grade
	Marking Ink	Pad Printing Ink	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
Endotracheal Tube Cuffed All Variants	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Blue Pigment	Pigment	Medical Grade
Endotracheal Tube Reinforced Plain All Variants	PVC Tube	Polyvinyl Chloride	Medical Grade
		SS Wire	Medical Grade
	Marking Ink	Pad Printing Ink	Medical Grade
	15 MM Connector	ABS	Medical Grade
Endotracheal Tube Reinforced Cuffed All Variants	PVC Tube	Polyvinyl Chloride	Medical Grade
		SS Wire	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade

	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Connector	ABS	Medical Grade
Endotracheal Tube Preformed North Nasal Plain (SMD 717)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Marking Ink	Pad Printing Ink	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
Endotracheal Tube Preformed North Nasal Cuffed (SMD 717 C)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Blue Pigment	Pigment	Medical Grade
Endotracheal Tube Preformed South Oral Plain (SMD 718 S)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Marking Ink	Pad Printing Ink	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
Endotracheal Tube Preformed South Oral Cuffed (SMD 718 SC)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Blue Pigment	Pigment	Medical Grade
Endotracheal Tube Cuffed with Subglottic Suction (SMD 722)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	Suction Tube	Polyvinyl Chloride	Medical Grade
	Suction Port	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Blue & Yellow Pigment	Pigment	Medical Grade
Endotracheal Tube Preformed Pearl/Ivory Nasal (SMD 754)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Blue Pigment	Pigment	Medical Grade
Endotracheal Tube Plain Silicone Elastomer Coated (SMD 701 SP)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Marking Ink	Pad Printing Ink	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Silicone Compound	Silicone Oil	Medical Grade
Endotracheal Tube Cuffed Silicone Elastomer Coated (SMD 701 SC)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade

	Silicone Compound	Silicone Oil	Medical Grade
	Blue Pigment	Pigment	Medical Grade
Endotracheal Tube Microlaryngeal Cuffed (SMD 765)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Blue Pigment	Pigment	Medical Grade
Endotracheal Tube with Tapered Cuff/Treachseal (SMD 701 CT)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Blue Pigment	Pigment	Medical Grade
Endotracheal Tube Cuffed with Blue Tip (SMD 772)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	Blue Tip	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Blue Pigment	Pigment	Medical Grade
Endotracheal Tube with Micro cuff (SMD 701 M)	PVC Tube	Polyvinyl Chloride	Medical Grade
	Cuff Balloon	Polyvinyl Chloride/PU	Medical Grade
	Marking Ink	Screen / Pad Printing Ink	Medical Grade
	Pilot Balloon	Polyvinyl Chloride	Medical Grade
	NRV	PVC, SS, PP, PE	Medical Grade
	Inflation Tube	Polyvinyl Chloride	Medical Grade
	15 MM Connector	Polypropylene (PP)	Medical Grade
	Blue Pigment	Pigment	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**
	**Do not use if packaging is damaged or Opened**		**Phthalate Free**		**Medical Device**		**Avoid Direct Sunlight**
	**Do not Reuse**		**MRI Conditional**		**CE Certification**		**Keep Dry**
	**Keep in a dry place between 5°C to 45°C**		**Sterile Barrier System**		**Unique Device Identifier**		

Mfd. By: Sterimed Group
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EC REP

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