INSTRUCTIONS FOR USE

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

NAME OF PRODUCT: SUCTION CATHETER (CLOSED SUCTION SYSTEM)

PRODUCT CODE: SMD 700 CS

PRODUCT DESCRIPTION:
PVC Closed tracheal suction systems (CTSS) allow the removal of tracheobronchial secretions without disconnecting ventilatory circuits, preventing alveolar derecruitment, gas exchange deterioration and hypoxia. It is intended for short term use.

INTENDED PURPOSE:

Used in critical care units to aspirate secretions from the patient's airway who has Endotracheal Tube or Tracheostomy tube and require mechanical ventilation. The system allows insertion or withdrawal of a Suction Catheter (Closed suction system) into trachea without disconnection from ventilator circuit and used for short term.

INDICATIONS:

Suctioning is indicated when the patient is unable to clear secretions and/or when there is audible or visible evidence of secretions in the large/central airways that persist in spite of the patient's best cough effort. Need for suctioning is evidenced by one or more of the following:

- Visible secretions in the airway
- Chest auscultation of coarse, gurgling breath sounds, rhonchi, or diminished breath sounds
- Reported feeling of secretions in the chest
- Suspected aspiration of gastric or upper airway secretions
- Clinically apparent increased work of breathing
- Restlessness
- Unrelieved coughing

INSTRUCTIONS FOR USE :

- Wash and disinfect your hand and wear sterile gloves aseptically.
- Check the packing carefully, if packing is found damaged, torned or pierced discard that piece.
- Open the package and remove all protective cover.
- Lift protection lid and connect suction control valve to suction line.
- Set vacuum to desired level while depressing suction control valve.
- Attach patient port to the tracheal/tracheostomy tube and Ventilator port to Ventilator circuit and, If needed interpose the catheter mount between circuit and double swivel elbow.
- Slide upward the patient access valve in the open position.
- Insert the suction catheter with one hand into tracheal/ tracheostomy tube to desired depth and maintain the grip on elbow connector with the other hand.
- Apply vacuum by depressing suction control valve, whilst withdrawing suction catheter.
- After suctioning, withdraw suction catheter until black tip marking is fully visible.
- To isolate suction catheter from airway, turn patient access valve down ward in the closed position.
- Ensure patient access valve is in closed position to isolate suction catheter from airway.
- Connect vial or syringe to flushing port and inject solution while applying suction by pressing control valve.
- Rotate suction catheter clockwise and remove it.

CONTRAINDICATIONS:

- Epiglottitis or croup
- Recent nasal, oral or esophageal surgery
- Severe bronchospasm or laryngeal spasm,

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- Irritable airway

INTENDED USER:

Trained and registered health care professional.

INTENDED PATIENT POPULATIONS:

Infants, Paediatrics and Adult

WARNINGS:

- The use of this product is restricted to a qualified Doctor or a Paramedic.

PRECAUTIONS AND CAUTIONS:

- Read instructions before use.
- Prior to use read entire instructions for use. Failure to do so may result in severe patient injury.
- **STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLECONSEQUANCES FROM IMPROPER USE.**
- Only then turn patient access valve, if black marking is fully visible.
- Do not use with a stylet or guidewire.
- Do not clean or Re-sterilize, for single use only. 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.

ADVERSE EFFECTS:

- Suctioning can stimulate the vagal nerve, predisposing the patient to bradycardia and hypoxia.
- Hypoxia can be profound from occlusion, interruption of oxygen supply, and prolonged suctioning.
- Mucosal trauma, physical injuries, and bleeding can result from blunt or penetrating trauma.
- Infections can result from the introduction of commensals into the respiratory tract.
- Pain and discomfort can result from suctioning.

CLINICAL BENEFITS:

- Easy to use
- Less time consuming
- Better tolerated by the patients
- CS could be performed with less staffing time and number of nurses
- Less physiological disturbances to patients
- No significant increases in adverse events.
- Reduced probability of ventilator associated pneumonia.
- Safer procedure

RESIDUAL RISKS:

- Anaphylaxis
- Hypoxia, Respiratory Distress, Low Saturation

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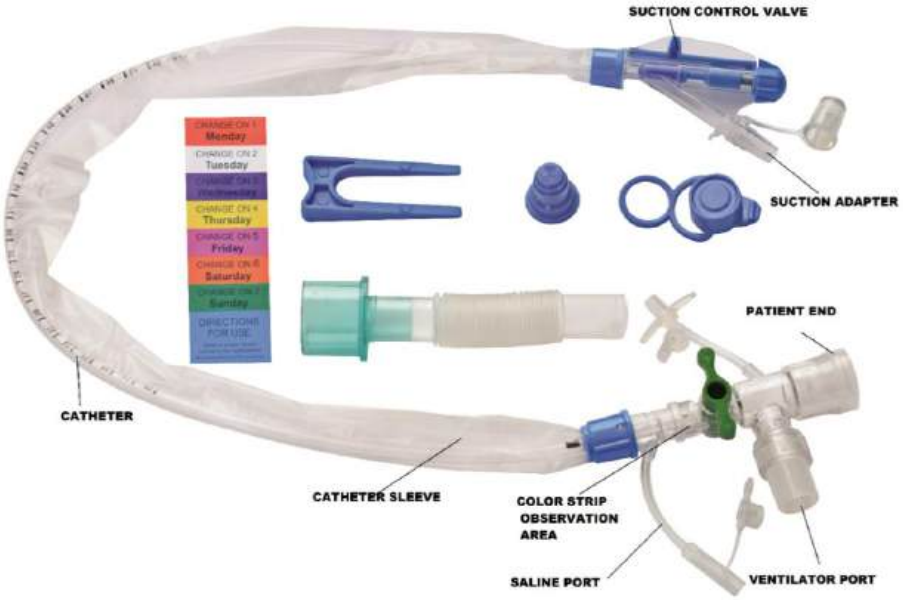
- Infection, Injury

SUPPLY:

Closed Suction System (SMD 700 CS)



MATERIAL USED:

Raw materials	Key Functions	Specification/ Material Grade
PVC Catheter	PVC	Medical Grade
Marking Ink	Screen / Pad Printing Ink	Medical Grade
Thumb Control Valve for CSS	ABS	Medical Grade
Double Swivel elbow connector	PP/ PC	Medical Grade
Catheter Sleeve	HDPE	Medical Grade
Isolation Chamber Control Valve	PVC/PP	Medical Grade
Pigment	Sea Green, Blue, Black White, Green, Orange Red, Yellow	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.

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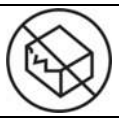
DEVICE DISPOSAL:

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		Sterile Barrier System		Avoid Direct Sunlight
	Do not Reuse		Keep Dry		CE Certification		Medical Device
	MRI Conditional		Keep in a dry place between 5°C to 45°C		Unique Device Identifier		

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