INSTRUCTIONS FOR USE

SUCTION CATHETER

(Plain, Thumb control, Fingertip control & Tiemann)

***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

SMDPL/IFU/SC/01 Rev. No.:00, Dt. 12.08.2023

PRODUCT DESCRIPTION:

Suction Catheter Plain (SMD 700 P): Transparent PVC Tubing without lateral eye and coloured Connector for suction to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi. It is intended for Transient use.

Suction Catheter Plain with Graduation (SMD 700 PG): Transparent PVC Tubing without lateral eye and coloured Connector for suction to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi. It is intended for Transient use.

Suction Catheter Thumb Control (SMD 700 ATC): Transparent PVC Tubing without lateral eye and coloured Connector for control suctioning to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi by using a thumb control connector. It is intended for Transient use.

Suction Catheter Thumb Control with Graduation (SMD 700 ATCG): Transparent PVC Tubing without lateral eye and coloured Connector for control suctioning to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi by using a thumb control connector. It is intended for Transient use.

Suction Catheter Fingertip Control (SMD 700 BFT): Transparent PVC Tubing without lateral eye and coloured Connector for control suctioning to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi by using a Finger Tip Control connector. It is intended for Transient use.

Suction Catheter Fingertip Control with Graduation (SMD 700 BFTG): Transparent PVC Tubing without lateral eye and coloured Connector for control suctioning to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi by using a Finger Tip Control connector. It is intended for Transient use.

Suction Catheter Tiemann Tip (SMD 700 T): Transparent PVC Tubing without lateral eye and coloured Connector to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi, catheter tip designed to atraumatic insertion. It is intended for Transient use.

Suction Catheter Tiemann Tip with Graduation (SMD 700 TG): Transparent PVC Tubing without lateral eye and coloured Connector to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi, catheter tip designed to atraumatic insertion. It is intended for Transient use.

INTENDED PURPOSE:

Suction catheter used to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi and used for transient use.

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

CONTRAINDICATIONS:

- Pharyngeal Obstruction
- Acute pulmonary edema

LIMITATION:

The maximum suction time should only be 15 seconds. After suctioning re-oxygenate the patient.

INTENDED USER

Trained and registered health care professional.

INTENDED PATIENT POPULATIONS:

Infants, Paediatrics and Adult

DIRECTIONS FOR USE:

- Choose the right Equipment.
- Open the package from the peel-open area and remove the device.
- Connect the catheter to the suction connection tubing.
- Slide the catheter along the oral/nasal cavity tracheal tube down to the trachea.
- Connect the Plain or Fingertip Control or Thumb Control or Atraumatic suction Connector of the catheter to the suction adaptor. While suctioning, cover the nozzle of the Thumb Control or Fingertip Control Connector accordingly to adjust the suction intensity.
- It can be used alone or in combination with tracheal tubes. Mainly used for suctioning sputum.

WARNING:

 # The use of this product is restricted to a qualified Doctor or Healthcare professional only. No need for specific hazard alert information before using the device.

PRECAUTIONS AND CAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury.
- ***STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE.***
- Do not clean or Re-use the device, 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 opening the packing.
- Do not use if the package is opened and damaged.
- Do not Re-sterile the Device.
- Do not use with a stylet or guide wire.
- Avoid forcing the Catheter
- Do not Suction Too long.
- Prolonged suctioning increases the risk of hypoxia and other complications.
- Do not use the device after expiry Date mentioned on the Label.
- If the patient is sensitive or allergic to PVC, do not use the device.

ADVERSE EVENTS:

- Mechanical trauma to the airway
- Bleeding
- Laryngospasm
- Bronchospasm
- Vasovagal stimulation
- Gagging
- Vomiting
- Ventilator Associated Pneumonia
- Respiratory arrest

CLINICAL BENEFIT

- Intubation success is 100%
- Takes less time
- Reduces the potential risk of nasal and tracheal injury
- Successful and rapid
- Lifesaving procedure requiring timely and precise methodology
- Rapid clinical improvement and a low tendency of relapse
- Safe and cost effective
- Improved clearance of secretions

RESIDUAL RISKS

- Anaphylaxis
- Hypoxia, Respiratory Distress and Low Saturation

INSTRUCTIONS FOR USE

SUCTION CATHETER

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- Infection, Injury

Supply:

Suction Catheter Plain (SMD 700 P) – Size 4 to 20 FG
Suction Catheter Thumb Control (SMD 700 ATC) – Size 4 to 20 FG Suction Catheter Fingertip Control (SMD 700 BFT) – Size 4 to 20 FG Suction Catheter Atraumatic (SMD 700 T) – Size 4 to 20 FG

Plain – SMD 700 P

Plain (With Graduation) – SMD 700 PG

Thumb Control – SMD 700 ATC

Thumb Control (With Graduation) – SMD 700 ATCG

Fingertip Control – SMD 700 BFT

Fingertip Control (With Graduation) – SMD 700 BFTG

Tiemann Tip – SMD 700 T

Tiemann Tip (With Graduation) – SMD 700 TG

MATERIAL USED:

Component	Material	Specification/Grade
Funnel Connector	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Fingertip Connector	Butadiene Styrene) Compound	
Thumb Control Connector	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Catheter (Tube)	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Chamber	PP (Poly Propylene) Compound	Medical Grade
Chamber Cap	PVC (Poly Vinyl Chloride) Compound	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 catheters.

STORAGE:

These products 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 catheters may be contaminated with infectious and/or other hazardous materials. Discard used catheters in the container meant for infectious waste. Unused expired catheters 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

SYMBOLS:

REF	**Catalogue No.**		**See instructions for Use**
	Cautions		**Keep Dry**
	Do not use it if the packaging is damaged.		**Sterile Barrier System**
	Single-Use	2 STERILIZE	**Do not Re-sterilize**
LOT	**Batch / Lot No.**	STERILE EO	**Ethylene Oxide Sterilized**
	Date of Mfg.	LATEX	**Latex Free**
	Date of Exp.	MD	**Medical Device**
	Avoid Direct Sunlight	45°C 5°C	**Keep in a dry place between 5°C to 45°C**

INSTRUCTIONS FOR USE

SUCTION CATHETER

(Plain, Thumb control, Fingertip control & Tiemann)

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PHT DEHP **Phthalate Free**

Pyrogen Free

UDI **Unique Device Identifier**

EC REP CE 0123

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Mfg. Lic. No.: MFG/MD/2018/000086

INSTRUCTIONS FOR USE

SUCTION CATHETER

(Infant Mucus Extractor)

***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

SMDPL/IFU/SC/01 Rev. No.:00, Dt. 12.08.2023

PRODUCT DESCRIPTION:

Suction Catheter with Mucus Trap (Infant Mucus Extractor) (SMD 803): PVC Infant Mucus extractor is a device that generates a weak, or low negative pressure used on new-born babies to clear blocked airways and must therefore have a limited negative pressure to avoid unintentional trauma. It is intended for Transient use.

Suction Catheter with Mucus Trap (Infant Mucus Extractor with Filter) (SMD 803 F): PVC Infant Mucus extractor is a device that generates a weak, or low negative pressure used on new-born babies to clear blocked airways and must therefore have a limited negative pressure to avoid unintentional trauma. It is intended for Transient use.

Suction Catheter with Mucus Trap (Infant Mucus Extractor with thumb Control and Graduation) (SMD 803 TG): PVC Infant Mucus extractor is a device that generates a weak, or low negative pressure used on new-born babies to clear blocked airways and must therefore have a limited negative pressure to avoid unintentional trauma. It is intended for Transient use.

Suction Catheter with Mucus Trap (Infant Mucus Extractor with Filter, thumb Control and Graduation) (SMD 803 FTG): PVC Infant Mucus extractor is a device that generates a weak, or low negative pressure used on new-born babies to clear blocked airways and must therefore have a limited negative pressure to avoid unintentional trauma. It is intended for Transient use.

INTENDED PURPOSE:

Suction catheter used to aspirate liquids or semisolids from a patient's pharynx, trachea, or bronchi and used for transient use.

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

CONTRAINDICATIONS:

There are no broad medical contraindications that prohibit all forms of airway management.

LIMITATION

The maximum suction time should only be 15 seconds. After suctioning re-oxygenate the patient.

INTENDED USER

Trained and registered health care professional.

INTENDED PATIENT POPULATIONS

Infants, Paediatrics

DIRECTIONS FOR USE:

- Check The packing carefully, if packing is found damaged or opened discard that device.
- Open the package from the peel-open area and remove the device.
- Connect the catheter to the suction connection tubing.
- Use an aspiration catheter to evacuate the mucus.
- Keep the reservoir chamber in an upright position during the suctioning procedure. The volume of the mucus can be checked with the scale provided on the chamber.
- Discard the device after a single use.

WARNING:

 # The use of this product is restricted to a qualified Doctor or Healthcare professional only. No need for specific hazard alert information before using the device.

CAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury.
- ***STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE.***
- Do not clean or Re-use the device, 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 opening the packing.
- Do not use if the package is opened and damaged.
- Do not Re-sterile the Device.
- Do not use a stylet or guide wire.
- Avoid forcing the Catheter
- Do not Suction Too long.
- Do not use the device after the expiry date mentioned on the Label.
- If the patient is sensitive or allergic to PVC, do not use the device.

ADVERRSE EVENTS:

- Mechanical trauma to the airway
- Bleeding
- Laryngospasm
- Bronchospasm
- Vasovagal stimulation
- Gagging
- Vomiting
- Ventilator Associated Pneumonia
- Respiratory arrest

CLINICAL BENEFIT

- Intubation success was 100%
- Takes less time
- Reduces the potential risk of nasal and tracheal injury
- Successful and rapid
- Lifesaving procedure requiring timely and precise methodology
- Rapid clinical improvement and a low tendency of relapse
- Safe
- Improved clearance of secretions

RESIDUAL RISKS

- Anaphylaxis
- Hypoxia, Respiratory Distress and Low Saturation
- Infection, Injury

Supply:

Suction Catheter with Mucus Trap (SMD 803) – Standard Size

INSTRUCTIONS FOR USE

SUCTION CATHETER

(Infant Mucus Extractor)

***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

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Suction Catheter with Mucus Trap (Infant Mucus Extractor) – SMD 803

Suction Catheter with Mucus Trap (Infant Mucus Extractor with Filter) – SMD 803 F

Suction Catheter with Mucus Trap (Infant Mucus Extractor with Thumb Control & Graduation) – SMD 803 TG

Suction Catheter with Mucus Trap (Infant Mucus Extractor with Filter, Thumb Control & Graduation) – SMD 803 FTG

MATERIAL USED:

Component	Material	Specification/Grade
Funnel Connector	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Fingertip Connector	ABS (Acrylonitrile Butadiene Styrene) Compound	Medical Grade
Thumb Control Connector	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Catheter (Tube)	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Chamber	PP (Poly Propylene) Compound	Medical Grade
Chamber Cap	PVC (Poly Vinyl Chloride) Compound	Medical Grade

STERILITY:

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

STORAGE:

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

DEVICE DISPOSAL:

Used catheters may be contaminated with infectious and/or other hazardous materials. Discard used catheters in the container meant for infectious waste. Unused expired catheters should be disposed of as per local regulations.

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SYMBOLS:

REF	**Catalogue No.**		**See instructions for Use**
	Cautions		**Keep Dry**
	Do not use it if the packaging is damaged.		**Sterile Barrier System**
	Single-Use	STERILIZE	**Do not Re-sterilize**
LOT	**Batch / Lot No.**	STERILE EO	**Ethylene Oxide Sterilized**
	Date of Mfg.	LATEX	**Latex Free**
	Date of Exp.	MD	**Medical Device**
	Avoid Direct Sunlight	45°C 5°C	**Keep in a dry place between 5°C to 45°C**
PHT DEHP	**Phthalate Free**		**Pyrogen Free**
UDI	**Unique Device Identifier**		

EC REP CE 0123

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