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Issue No.:	04
Rev. No.:	03
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Romsons®

SUCTION CATHETER®

(Endo-bronchial Suction Catheter-Plain)

REF GS-2006

℞ ONLY

INSTRUCTIONS FOR USE

The device is biocompatible, Non-Toxic, Non-Pyrogenic , Phthalate Free, Sterile, Single Use.

⚠ **Caution :** Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications..This device is Sterile & Ready for Use. Sterility is guaranteed – if pack is undamaged. The device is for Single Use Only.

Device Description : Endo bronchial suction catheters, intended for removal of secretions by suctioning through attachment to suction apparatus. Endo bronchial Suction Catheter consists of a soft, frozen surface tube with an open tip that is smooth, well rounded, edge free, burr free. This distal open tip is preceded by one or more edge free, smooth surface lateral eye/s for enabling efficient drainage. Proximal end consists of a universal funnel connector for connection to the controlled / regulated suction apparatus.

Population of Use : Adults & Paediatrics.

Intended User- To be administered by an expert qualified medical professional.

Intended Use : Suction catheter is sterile, single use device intended for removal of secretions from mouth/ pharynx/trachea/bronchial tubes in critically ill patients with weakened ability to spontaneously clear secretions / debris. For instant use only. Immediately discard the device after use.

Preferred Route of Administration: Oral Cavity / Nasal Cavity & Tracheal opening (tracheostomy).

Contents : Suction Catheter one unit, Sterile, individually packed in a peel open pack.

Size : FG-5, 6, 8, 10, 12, 14, 16, 18.

Material of Construction : Poly Vinyl Chloride, Master Batch.

Storage : Store in a cool & dry place.

Indications : Retained secretions causing patient's distress or physiological derangement. Ineffective cough & unable to clear secretions spontaneously. To maintain airway patency. To stimulate cough. To obtain sputum sample, etc.

Contraindications : Hypersensitivity to device material ,Severe bleeding disorder, unexplained hemoptysis, Severe bronchospasm, Irritable airway, Facial injury, Recent nasal, oral or esophageal surgery, Loose teeth/denture, Hemodynamic instability, Tracheo / oesophageal fistulae, Severe gag reflex, Increased intra-cranial pressure, Occluded nasal passage, nasal bleeding, etc.

Potential Complications / Risks : Mechanical Trauma to the airway, Bleeding, Hypoxia, Hypoxemia, Cardiac arrhytmias, Vasovagal stimulation, Gagging, Vomiting, Aspiration, Pain/Distress/Discomfort, Laryngospasm/ Bronchospasm, Respiratory arrest, Atelectasis, Infection, Lesions in tracheal mucosa, Ventilator Associated Pneumonia, etc.

Warnings : This device is intended for Single use only.

Do not put the Device to Use after the Use by Date or
mpromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factor, rendering the devicDate of Expiry.
DO NOT resterilize and /or reuse the device, as this can coe non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
Re-use of single use device creates a potential risk for patient or use. It may lead to contamination and/or impairment of functional capability.
Contamination and / or limited functionality of the device may lead to injury, illness of the patient.

Precautions :

(i) Check the integrity and functionality of the suction catheter before use. Do not use if the Unit Pack is open or damaged.
(ii) Determine patient's condition and vitals status During device application / Operation.
(iii) Check the patency of the device before use.
(iv) Destroy / Dispose the device & its accessories after single use as bio-medical waste as per applicable laws.
(v) Do not Resterilize. Do not Re-use. Discard after single use.
(vi) Check for controlled / validated suction apparatus / suction line before use.

Adverse Events : Mechanical trauma to the airway, Bleeding, Vasovagal stimulation, Laryngospasm, Bronchospasm, Gagging, Vomiting, Ventilator Associated Pneumonia, Respiratory arrest, etc.

General Instructions :

To be administered by an expert qualified medical professional. Use maximal sterile barrier precautions during administration
(These are only the guidelines & hence, user's medical experience / expertise in important).

Use Instructions :

(1) Suction Catheter is intended for endo-bronchial suction from Oro-pharyngeal & Tracheo-bronchial regions.
(2) Check the packing carefully, if packing is found damaged, torn or pierced, discard the piece. Ensure proper selection of size before use.
(3) Use personal protective equipment (mask, eye or face shield, gown, etc.) as per infection prevention & control.
(4) Peel open the pack & remove the device carefully.
(5) Check the integrity / patency of the device.
(6) Connect the universal funnel connector of suction catheter to the regulated / controlled vacuum source.
(7) Without applying suction pressure, gently insert the Suction Catheter distal end-smooth, soft & coned open tip suitably into the oro-pharyngeal cavity / patient's airway as per case. Either, directly or through already in-dwelled Guedel Airways/ Tracheal Tube/ Tracheotomy Tube / Closed Suction System, etc.
(8) Clear any visible secretion before inserting the suction catheter deep into patient's nare, mouth or artificial airway.
(9) Do not force catheter in when experiencing resistance, reinsert catheter if needed.
(10) Stimulate cough if it does not occur naturally.
(11) Withdraw catheter slightly (1-2mm) prior to applying suction.
(12) Apply suction only when withdrawing catheter in a rotating manner.
(13) No need to rotate catheter if using an in-line/closed suction system.
(14) Total suction duration should not exceed 15 seconds.
(15) Rest between suction passes; closely monitoring patient vitals, discomfort and condition; calm patient if necessary.
(16) Observe secretion aspirated (e.g. Amount, color, tenacity, any blood in secretion, etc.)
(17) Rinse suction catheter if necessary.

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CE 2460

Basic UDI DI : 8902120B008RV

REF	**Catalogue Number**	MD	**Medical Device**		**Donot Reuse**		**Consult Instructions for Use**
LOT	**Batch Code**	IN	**Country of Manufacture**		**Do Not Re-sterilize**		**Keep away from sunlight**
	Date of Manufacture	STERILE EO	**Sterilized Using Ethylene Oxide**	UDI	**Unique device Identifier**		**Keep Dry**
	Use by date		**Non-pyrogenic**		**Do Not Use if Pack is Damaged and Consult Instructions for Use**		**Caution**
	Manufacturer	EC REP	**Authorized Representative in the European Union**		**Single Sterile barrier system**	40 °C (104 °F) 10 °C (50 °F)	**Temperature Limit**