Instructions for use

CE 2797

[Product Name]

Suction Catheter

[Intended Use]

It is intended for use in suctioning of the respiratory tract for clinical patients.

[Component]

This product is mainly composed of shaft (made of medical non-toxic PVC material) and connector.

[Type and Specification]

Type	Specification	REF
Type I	Fr6	SC06TP
	Fr8	SC08TP
	Fr10	SC010TP
	Fr12	SC012TA
	Fr14	SC014TA
	Fr16	SC016TA
Type II	Fr6	SC06CP
	Fr8	SC08CP
	Fr10	SC010CP
	Fr12	SC012CA
	Fr14	SC014CA
	Fr16	SC016CA
Type III	Fr6	SC06YP
	Fr8	SC08YP
	Fr10	SC010YP
	Fr12	SC012YA
	Fr14	SC014YA
	Fr16	SC016YA
Type IV	Fr6	SC060P
	Fr8	SC080P
	Fr10	SC0100P
	Fr12	SC0120A
	Fr14	SC0140A
	Fr16	SC0160A

[Indication]

Unable to clear secretions spontaneously.

[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.

[Patient target group]

Suitable for patients who need sputum aspiration.

[Intended users]

Healthcare professional.

[Use Method]

1. Choose an appropriate suction catheter.
2. Check whether the single package of the product is intact before use.
3. Strictly implement Sterile operation technology.
4. Open the package and take out the suction catheter.
5. Lubricate the suction catheter with salt water.
6. The connecting tube of the electric suction apparatus connects the machine end of the suction catheter.
7. Insert the patient end of the suction catheter slowly into the patient's respiratory tract.
8. The negative pressure was turned on and sputum aspiration was performed using intermittent breathing techniques.
9. After sputum aspiration is completed, pull out the suction catheter and turn off the negative pressure.

[Warnings and Precautions]

1. The product has been sterilized with ethylene oxide with validity for five years.
2. This product is for single use. Do not reuse, reprocess or resterilize. Reuse of the device poses a potential risk of serious injury and/or infection. 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.
3. This product comes into contact with mucosa, which can be contaminated. Care should be taken in the handling and disposal of the device after use to prevent contamination. The disposal procedures shall be handled harmlessly by qualified or authorized institutions according to the local relevant regulations.
4. Check whether the package is complete. If the package is damaged, do not use it.
5. Strictly limit the suction pressure below 0.014Mpa.
6. Strictly limit the suction time (15s/ time).
7. Although negative pressure suction can remove respiratory secretions, it can also suck oxygen-rich gases out of the respiratory tract, which can cause severe hypoxemia if monitored and applied improperly.
8. In respiratory tract aspiration, the time of applying negative pressure should be limited to 15s, and the time of leaving the ventilator should not exceed 20s. After removing the suction catheter, ventilation and oxygen inhalation must be re-given.
9. The stability and tolerance of the patient should be closely monitored during suction. If the patient has tension and arrhythmia, it should be stopped immediately, and ventilation and oxygen should be given.
10. The suction catheter can be used in combination with endotracheal tube, Reinforced endotracheal tube,

laryngeal mask airway and other devices. When the suction catheter is used together, it must first ensure that it can be smoothly inserted into the lumen of the device and has sufficient length. If sputum aspiration operation is required during ventilation, it should be carried out according to the corresponding operating procedures (Note: Whether mechanical ventilation needs to be interrupted during operation is judged by the doctor). Special attention should be paid to the outer diameter of the part inserted with the suction catheter. Too large an outer diameter will produce too strong suction negative pressure. Due to insufficient space for air to be involved around the suction catheter, atelectasis will occur, and the removal ability of secretions with too small an outer diameter is limited.

11. Before use, you must understand the use method and function of the product in detail to ensure safe and effective use.
12. This product needs to be operated and used by healthcare professional.
13. Please inform the manufacturer in case of any incidents related to the device occur and report to the competent authority of the Member State in which the incidents occurred, if applicable.

[Side effects]

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.

[Shelf-life]

5 years

[Clinical lifetime]

Less than 15s/time

[Intended clinical benefits]

Suction catheter can effectively and rapidly suck out the secretions in the respiratory tract of patients within 15 seconds per time.

[Sterilization Method]

Ethylene oxide

[Storage and Transport Conditions]

1) No heavy pressure, direct sunlight and rain and snow immersion, so as not to damage the equipment
2) Handling process should be handled gently to avoid violent collision
3) Keep away from fire and heat sources to avoid heat deformation of the instrument
4) Store in a cool and dry place with good ventilation and no corrosive gases.

[Production Date]

See on the package.

[Symbol Explanation]

	Manufacturer	CN	Date of manufacture, Country of manufacture
EC REP	Authorized representative in the European Community/ European Union	LOT	Batch code
	Use-by date		Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use		Caution
	Do not resterilize, Indicates a medical device that is not to be resterilized		Do not re-use
	Single sterile barrier system	STERILE EO	Sterilized using ethylene oxide
MD	Medical device	UDI	Unique device identifier
CE 2797	CE Marking	REF	Catalogue number
	Keep away from sunlight		Keep dry
5	Stacking layer limit		Fragile, handle with care

[Manufacturer]
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[Issue date]

YYYY-MM-DD

[Latest revision]

A/3